

Report to Congress

Premarket Approval of Pediatric Uses of Devices

FY 2019 – FY 2020

**Submitted Pursuant to
Section 515A of the Federal Food, Drug, and Cosmetic Act**



Executive Summary

Section 515A(a)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) requires the Food and Drug Administration (FDA or Agency) to submit an annual report to Congress on premarket approvals for devices labeled¹ for pediatric use, among other requirements. This report also includes information on the premarket approval of devices where there is a pediatric subpopulation² that suffers from the disease or condition that the device is intended to treat, diagnose, or cure. This report includes statistical data on these approvals, which were approved by FDA's Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER) during fiscal year (FY) 2019 (October 1, 2018, through September 30, 2019) and FY 2020 (October 1, 2019, through September 30, 2020). This is the tenth such report submitted by FDA to Congress.

As noted in this report, during FY 2019 and FY 2020, FDA approved 119 premarket device applications. In particular, in FY 2019,

- FDA approved 53 original and panel-track supplement premarket approval (PMA) applications and three humanitarian device exemption (HDE) applications for devices. A total of 56 approvals.
- Of those 56 device approvals, FDA approved eight PMAs and two HDEs (or 10/56, 18 percent) for devices that were indicated for use in a pediatric population or subpopulation.^{3,4}
- Of the remaining 46 device approvals, 45 PMAs and one HDE were for devices that were indicated for use in adults. Of these 46 device approvals, the 45 PMAs (or 98 percent) were for devices that were determined to treat, diagnose, or cure a disease or condition for which there is a pediatric subpopulation that also suffers from such a disease or condition.⁵

¹ See section 201(k) of the FD&C Act for the definition of *label*; see 21 CFR 1.3 for the definition of *labeling*.

² Section 520(m)(6)(E)(i) of the FD&C Act (and 21 CFR 814.3(s)) defines *pediatric patients* as patients 21 years of age or younger at the time of their diagnosis or treatment. Section 515A(c) of the FD&C Act defines, by reference to section 520(m)(6)(E)(ii) of the FD&C Act, a *pediatric subpopulation* as one of the following subpopulations: neonates, infants, children, and adolescents.

³ More information about these FY 2019 pediatric device approvals, including these devices' review times and the pediatric population for which they were indicated at the time of their initial approval, appears in Appendix A of this report.

⁴ See section 515A(a)(3)(C) and 515A(a)(3)(D) of the FD&C Act.

⁵ See section 515A(a)(3)(A) of the FD&C Act.

- For two of the above-mentioned PMAs, FDA relied on data from adults to support its determination that the devices were reasonably assured to be safe and effective in pediatric patients.⁶
- For no device approvals, FDA relied on data from one pediatric subpopulation to support a determination of a reasonable assurance of safety and effectiveness in another pediatric subpopulation.⁷
- From the 53 PMA approvals, no PMA for a device that was indicated solely for a pediatric population was exempted from user fees.⁸
- The median time to review the eight PMAs for devices that were indicated for use in a pediatric population or subpopulation was 180 FDA Days⁹ and 427 Total Elapsed Days.
- The median time to review the two HDEs for devices that were indicated for use in a pediatric population or subpopulation was 138 FDA Days and 481 Total Elapsed Days.¹⁰
- Based on a review of the data available to FDA, such as the PMA and HDE periodic reports¹¹ received in FY 2019, there were 45 additional devices for which data available indicated that approved pediatric labeling could confer a benefit to pediatric patients regarding devices used in pediatric patients but not labeled for such use.¹²

In FY 2020,

- FDA approved 63 original and panel-track supplement PMAs and zero HDEs. A total of 63 approvals.

⁶ See section 515A(a)(3)(G) of the FD&C Act.

⁷ See section 515A(a)(3)(H) of the FD&C Act.

⁸ See section 515A(a)(3)(E) of the FD&C Act. Please note that under section 738(a)(2)(B)(i) of the FD&C Act, HDEs are exempt from user fees.

⁹ FDA's Medical Device User Fee Amendments of 2017 (MDUFA IV) commitment letter defined *FDA Days* as calendar days when a submission is considered to be under review at the Agency for submissions that have been filed. Tracking of FDA Days begins on the date of the receipt of the submission or the amendment to the submission that enables the submission to be filed. See FDA's final guidance document entitled *FDA and Industry Actions on Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Goals* (October 2017), available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-premarket-approval-applications-pmas-effect-fda-review-clock-and-goals>.

¹⁰ See section 515A(a)(3)(F) of the FD&C Act.

¹¹ PMAs are subject to any periodic postmarket reporting requirements imposed in the PMA approval order (see 21 CFR 814.82(a) and 21 CFR 814.84(b)). Similarly, under 21 CFR 814.126(b), "the holder of an approved HDE" must submit a periodic reports in accordance with the HDE approval order.

¹² Section 515A(a)(3)(B) of the FD&C Act.

- Of those 63 device approvals, FDA approved 26 PMAs and zero HDEs (or 26/63, 41 percent) for devices that were indicated for use in a pediatric population or subpopulation.
- Of the remaining 37 device approvals, 37 PMA and zero HDEs were for devices that were indicated for use in adults. Of these 37 device approvals, the 37 PMAs (or 100 percent) were for devices that were determined to treat, diagnose, or cure a disease or condition for which there is a pediatric subpopulation that also suffers from such a disease or condition.
- For one of the above-mentioned PMAs, FDA relied on data from adults to support its determination that the device was reasonably assured to be safe and effective in pediatric patients.
- For one of the above-mentioned PMAs , FDA relied on data from one pediatric subpopulation to support its determination that the device was reasonably assured to be safe and effective in another pediatric subpopulation.
- From the 63 PMA approvals, four PMAs for devices that were indicated solely for a pediatric population were exempted from user fees.
- The median time to review the 26 PMAs for devices that were indicated for use in a pediatric population or subpopulation was 180 FDA Days and 400 Total Elapsed Days.
- Based on a review of the data available to FDA, such as the PMA and HDE periodic reports received in FY 2020, there were 29 additional devices for which data available indicated that approved pediatric labeling could confer a benefit to pediatric patients regarding devices used in pediatric patients but not labeled for such use.

Table of Contents

I.	Introduction	1
II.	Background.....	2
III.	Summary of the Information Required by Section 515A(a)(3) of the FD&C Act	4
	<i>A. FY 2019.....</i>	<i>4</i>
	<i>B. FY 2020.....</i>	<i>6</i>
IV.	Conclusion.....	9
Appendix A:	The Devices Indicated for Use in Pediatric Populations Approved from FY 2019 to FY 2020	11
	<i>A. FY 2019 Approvals of, and Review Times for, PMA and HDEs for Devices Indicated for Use in Pediatric Populations</i>	<i>11</i>
	<i>B. FY 2020 Approvals of, and Review Times for, PMA and HDEs for Devices Indicated for Use in Pediatric Populations</i>	<i>17</i>
Appendix B:	PMA and HDE Approvals for Devices with a Pediatric Indication from FY 2008 to FY 2020 by CDRH and CBER	31
I.	Introduction	1
II.	Background.....	2
III.	Summary of the Information Required by Section 515A(a)(3) of the FD&C Act	4
	<i>A. FY 2019.....</i>	<i>4</i>
	<i>B. FY 2020.....</i>	<i>6</i>
IV.	Conclusion.....	9
Appendix A:	The Devices Indicated for Use in Pediatric Populations Approved from FY 2019 to FY 2020	11
	<i>A. FY 2019 Approvals of, and Review Times for, PMA and HDEs for Devices Indicated for Use in Pediatric Populations</i>	<i>11</i>
	<i>B. FY 2020 Approvals of, and Review Times for, PMA and HDEs for Devices Indicated for Use in Pediatric Populations</i>	<i>17</i>

**Appendix B: PMA and HDE Approvals for Devices with a Pediatric Indication from
FY 2008 to FY 2020 by CDRH and CBER 31**

I. Introduction

The Food and Drug Administration Amendments Act of 2007 (FDAAA)¹ amended section 515A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360e-1). Section 515A(a)(2) of the FD&C Act, as added by FDAAA, requires persons who are submitting a certain device application and seeking approval for that application to include in their application, if readily available, (1) a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure and (2) the number of affected pediatric patients.² Section 515A(a)(3) of the FD&C Act, as added by FDAAA, requires the Food and Drug Administration (FDA or Agency) to submit an annual report to Congress on the premarket approvals of devices labeled³ for pediatric use or for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure. On August 18, 2017, section 515A(a)(3) of the FD&C Act was amended by the FDA Reauthorization Act of 2017 (FDARA)⁴ to now also require, among other things, FDA to provide, in that annual report, information related to the number of devices approved with a pediatric indication. Specifically, section 515A(a)(3) of the FD&C Act, as amended, states that,

Not later than 18 months after the date of the enactment of this section and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes:

- (A) *the number of devices approved in the year preceding the year in which the report is submitted, for which there is a pediatric subpopulation that suffers from the disease or condition the device is intended to treat, diagnose, or cure;*
- (B) *any information, based on a review of data available to the Secretary, regarding devices used in pediatric patients but not labeled for such use for which the Secretary determines that approved pediatric labeling could confer a benefit to pediatric patients;*

¹ Public Law 110-85.

² Section 520(m)(6)(E)(i) of the FD&C Act (and 21 CFR 814.3(s)) defines *pediatric patients* as patients 21 years of age or younger at the time of their diagnosis or treatment. Section 515A(c) of the FD&C Act defines, by reference to section 520(m)(6)(E)(ii) of the FD&C Act, a *pediatric subpopulation* as one of the following subpopulations: neonates, infants, children, and adolescents.

³ See section 201(k) of the FD&C Act for the definition of *label*; see 21 CFR 1.3 for the definition of *labeling*.

⁴ Public Law 115-52.

- (C) *the number of pediatric devices that receive a humanitarian use exemption under section 520(m);*
- (D) *the number of devices approved in the year preceding the year in which the report is submitted, labeled for use in pediatric patients;*
- (E) *the number of pediatric devices approved in the year preceding the year in which the report is submitted, exempted from a fee pursuant to section 738(a)(2)(B)(v);*
- (F) *the review time for each device described in subparagraphs (A), (C), (D), and (E);*
- (G) *the number of devices for which the Secretary relied on data with respect to adults to support a determination of a reasonable assurance of safety and effectiveness in pediatric patients; and*
- (H) *the number of devices for which the Secretary relied on data from one pediatric subpopulation to support a determination of a reasonable assurance of safety and effectiveness in another pediatric subpopulation.*

For the items described in this paragraph, such report shall disaggregate the number of devices by pediatric subpopulation.

This is the tenth report of FDA submitted to Congress pursuant to section 515A(a)(3) of the FD&C Act since FDAAA's enactment. This combined fiscal year (FY) 2019 and FY 2020 report includes information and accounting on the premarket approvals of devices made during FY 2019 and FY 2020 that are, among other requirements, indicated for use in pediatric patients or that are intended to treat, diagnose, or cure diseases from which pediatric patients suffer.⁵ This report also includes background information regarding section 515A of the FD&C Act and FDA's implementation of that provision. Information submitted under section 515A(a) of the FD&C Act assisted in the development of this report.

II. Background

Section 515A of the FD&C Act, and other provisions in FDAAA and FDARA, are intended to encourage the development of devices for use in pediatric patients. For example, the Congressional House Report for FDAAA described the need for the legislation as follows:⁶

⁵ The phrase *indications for use*, as defined in 21 CFR 814.20(b)(3)(i), describes the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended.

⁶ House Committee on Energy and Commerce, "Food and Drug Administration Amendments Act of 2007," H.R.100-225, 110th Congress, 1st Session, on page 8.

Pediatric medical devices are used to treat or diagnose diseases and conditions in patients from birth through age 21 years. Some products are designed specifically for children, while others are borrowed from adult applications or produced for more general use.

Children have specific medical needs that must be considered when medical and surgical devices are prescribed. Devices that have not been studied for use in children may not accommodate the unique needs of children, such as allowing for expandable growth and accommodating their active lifestyles and differing metabolism.

Section 520(m)(6)(E)(i) of the FD&C Act defines *pediatric patients*, for device purposes, as patients who are 21 years of age or younger (i.e., from birth through the day prior to their 22nd birthday) at the time of diagnosis or treatment. Additionally, a *pediatric subpopulation* is defined by section 520(m)(6)(E)(ii) of the FD&C Act (and adopted by reference in section 515A(c) of the FD&C Act) as one of the following subpopulations: neonates, infants, children, and adolescents. Generally, FDA views the approximate age ranges for these pediatric subpopulations as follows:⁷

- Neonates (birth until 1 month of age);
- Infants (greater than 1 month of age until 2 years of age);
- Children (greater than 2 years of age until 12 years of age); and
- Adolescents (greater than 12 years of age through 21 years of age (i.e., up to but not including the 22nd birthday)).

On January 10, 2014, FDA issued a final rule in the *Federal Register*⁸ that amended 21 CFR part 814's regulations on the premarket approval of devices to now require persons who are submitting a certain device application and seeking approval for that application to include in their application, if readily available, (1) a description of any pediatric subpopulations that suffer from the disease or condition that a device is intended to treat, diagnose, or cure and (2) the number of affected pediatric patients. These requirements are mandated under section 515A of the FD&C Act, as amended by FDAAA and FDARA.

On March 24, 2014, FDA issued a final guidance document entitled *Premarket Assessment of Pediatric Medical Devices*, which provides information for applicants regarding the pediatric information requirement mandated under section 515A of the FD&C Act and its implementing

⁷ See FDA's final guidance document entitled *Premarket Assessment of Pediatric Medical Devices*, available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-assessment-pediatric-medical-devices>.

⁸ *Pediatric Uses of Devices; Requirement for Submission of Information on Pediatric Subpopulations That Suffer from a Disease or Condition That a Device Is Intended To Treat, Diagnose, or Cure* (79 FR 1735 at 1735-1741) (January 10, 2014).

regulations.⁹ On May 1, 2014, FDA issued a final guidance document entitled *Providing Information about Pediatric Uses of Medical Devices*.¹⁰

Later, on June 21, 2016, FDA issued a final guidance document entitled *Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices*.¹¹ This guidance document seeks to provide clarity and predictability for device sponsors and to ensure consistency within FDA regarding the specific criteria that should be considered when deciding whether leveraging existing clinical data to support pediatric device indications in premarket approval (PMA) applications, humanitarian device exemption (HDE) applications, and De Novo requests is appropriate and, if so, to what extent.

III. Summary of the Information Required by Section 515A(a)(3) of the FD&C Act

Per section 515A of the FD&C Act, this report provides data on premarket device approvals that were approved by FDA's Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER) during FY 2019 and FY 2020:

A. FY 2019

- FDA approved 53 original and panel-track supplement premarket approval (PMA) applications and three humanitarian device exemption (HDE) applications for devices. A total of 56 approvals.
- Of those 56 device approvals, FDA approved eight PMAs and two HDEs (or 10/56, 18 percent) for devices that were indicated for use in a pediatric population or subpopulation.^{12,13}
- Of the remaining 46 device approvals, 45 PMAs and one HDE were for devices that were indicated for use in adults. Of these 46 device approvals, the 45 PMAs (or 98 percent) were for devices that were determined to treat, diagnose, or cure a disease or condition

⁹ This final guidance document, published in March 2014, is available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-assessment-pediatric-medical-devices>.

¹⁰ This final guidance document, published in May 2014, is available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-information-about-pediatric-uses-medical-devices>.

¹¹ This final guidance document, published in June 2016, is available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/leveraging-existing-clinical-data-extrapolation-pediatric-uses-medical-devices>.

¹² More information about these FY 2019 pediatric device approvals, including these devices' review times and the pediatric population for which they were indicated at the time of their initial approval, appears in Appendix A of this report.

¹³ See section 515A(a)(3)(C) and 515A(a)(3)(D) of the FD&C Act.

for which there is a pediatric subpopulation that also suffers from such a disease or condition.¹⁴

- For two of the above-mentioned PMAs, FDA relied on data from adults to support its determination that the devices were reasonably assured to be safe and effective in pediatric patients.¹⁵
- For no device approvals, FDA relied on data from one pediatric subpopulation to support a determination of a reasonable assurance of safety and effectiveness in another pediatric subpopulation.¹⁶
- From the 53 PMA approvals, no PMA for a device that was indicated solely for a pediatric population was exempted from user fees.¹⁷
- The median time to review the eight PMAs for devices that were indicated for use in a pediatric population or subpopulation was 180 FDA Days¹⁸ and 427 Total Elapsed Days.
- The median time to review the two HDEs for devices that were indicated for use in a pediatric population or subpopulation was 138 FDA Days and 481 Total Elapsed Days.¹⁹
- Based on a review of the data available to FDA, such as the PMA and HDE periodic reports²⁰ received in FY 2019, there were 45 additional devices for which data available indicated that approved pediatric labeling could confer a benefit to pediatric patients regarding devices used in pediatric patients but not labeled for such use.²¹

¹⁴ See section 515A(a)(3)(A) of the FD&C Act.

¹⁵ See section 515A(a)(3)(G) of the FD&C Act.

¹⁶ See section 515A(a)(3)(H) of the FD&C Act.

¹⁷ See section 515A(a)(3)(E) of the FD&C Act. Please note that under section 738(a)(2)(B)(i) of the FD&C Act, HDEs are exempt from user fees.

¹⁸ FDA's Medical Device User Fee Amendments of 2017 (MDUFA IV) commitment letter defined *FDA Days* as calendar days when a submission is considered to be under review at the Agency for submissions that have been filed. Tracking of FDA Days begins on the date of the receipt of the submission or the amendment to the submission that enables the submission to be filed. See FDA's final guidance document entitled *FDA and Industry Actions on Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Goals* (October 2017), available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-premarket-approval-applications-pmas-effect-fda-review-clock-and-goals>.

¹⁹ See section 515A(a)(3)(F) of the FD&C Act.

²⁰ PMAs are subject to any periodic postmarket reporting requirements imposed in the PMA approval order (see 21 CFR 814.82(a) and 21 CFR 814.84(b)). Similarly, under 21 CFR 814.126(b), "the holder of an approved HDE" must submit a periodic report in accordance with the HDE approval order.

²¹ Section 515A(a)(3)(B) of the FD&C Act.

B. FY 2020

- FDA approved 63 original and panel-track supplement PMAs and zero HDEs. A total of 63 approvals.
- Of those 63 device approvals, FDA approved 26 PMAs and zero HDEs (or 26/63, 41 percent) for devices that were indicated for use in a pediatric population or subpopulation.
- Of the remaining 37 device approvals, 37 PMAs and zero HDEs were for devices that were indicated for use in adults. Of these 37 device approvals, the 37 PMAs (or 100 percent) were for devices that were determined to treat, diagnose, or cure a disease or condition for which there is a pediatric subpopulation that also suffers from such a disease or condition.
- For one of the above-mentioned PMAs, FDA relied on data from adults to support its determination that the device was reasonably assured to be safe and effective in pediatric patients.
- For one of the above-mentioned PMAs, FDA relied on data from one pediatric subpopulation to support its determination that the device was reasonably assured to be safe and effective in another pediatric subpopulation.
- From the 63 PMAs, four PMAs for devices that were indicated solely for a pediatric population were exempted from user fees.
- The median time to review the 26 PMAs for devices that were indicated for use in a pediatric population or subpopulation was 180 FDA Days and 400 Total Elapsed Days.
- Based on a review of the data available to FDA, such as the PMA and HDE periodic reports received in FY 2020, there were 29 additional devices for which data available indicated that approved pediatric labeling could confer a benefit to pediatric patients regarding devices used in pediatric patients but not labeled for such use.

From FY 2008 to FY 2020, 644 PMA and HDEs have been approved by CDRH and CBER combined, with an average of 49.54 device approvals per year.²² Of these device approvals, 170²³ were approved with an indication for use in a pediatric population or subpopulation at the initial time of the marketing authorization. Since FY 2008, as shown in Figure 1A, there has generally been an increase in PMA and HDE approvals, with non-pediatric indications of devices reviewed by CDRH and CBER.²⁴ From FY 2008 to FY 2020, the greatest number (i.e., 73) of

²² See Table 1 in Appendix B.

²³ This number was obtained by totaling the PMA and HDE approvals for devices indicated for pediatric patients from FY 2008 to FY 2020; see Table 1 in Appendix B.

²⁴ See also Table 1 in Appendix B.

PMA or HDE approvals was in FY 2016, and the lowest number of PMA or HDE approvals (i.e., 21) was in FY 2010.²⁵

Figure 1A demonstrates the PMA and HDE approvals, from FY 2008 to FY 2020, with pediatric indications (black) and non-pediatric (red) indications of devices reviewed by CDRH and CBER.

Figure 1A. PMA and HDE Approvals from FY 2008 to FY 2020 for Devices with Pediatric Indications and Non-Pediatric Indications.

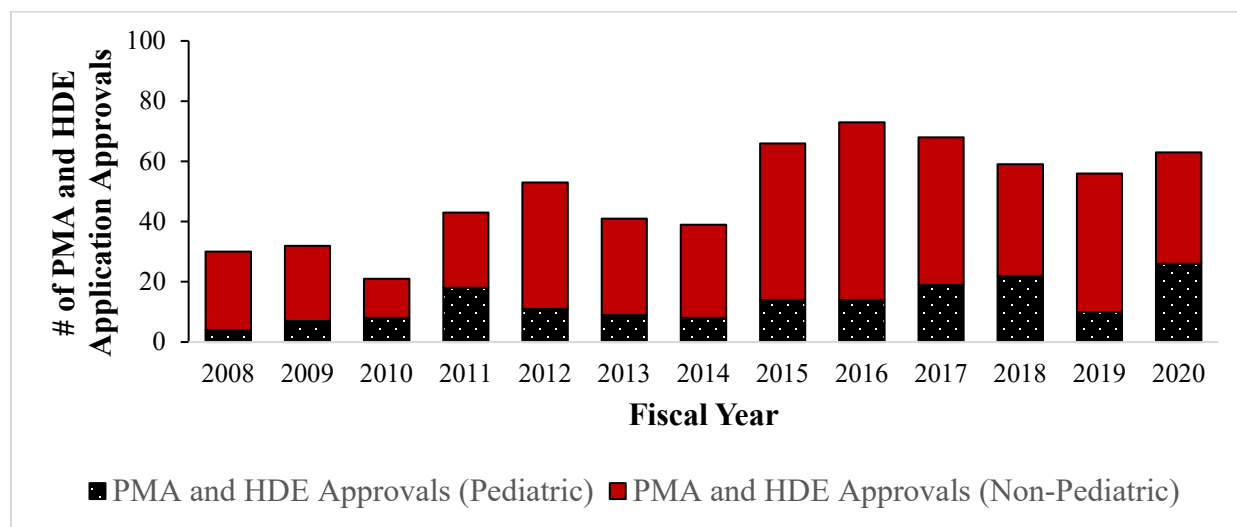
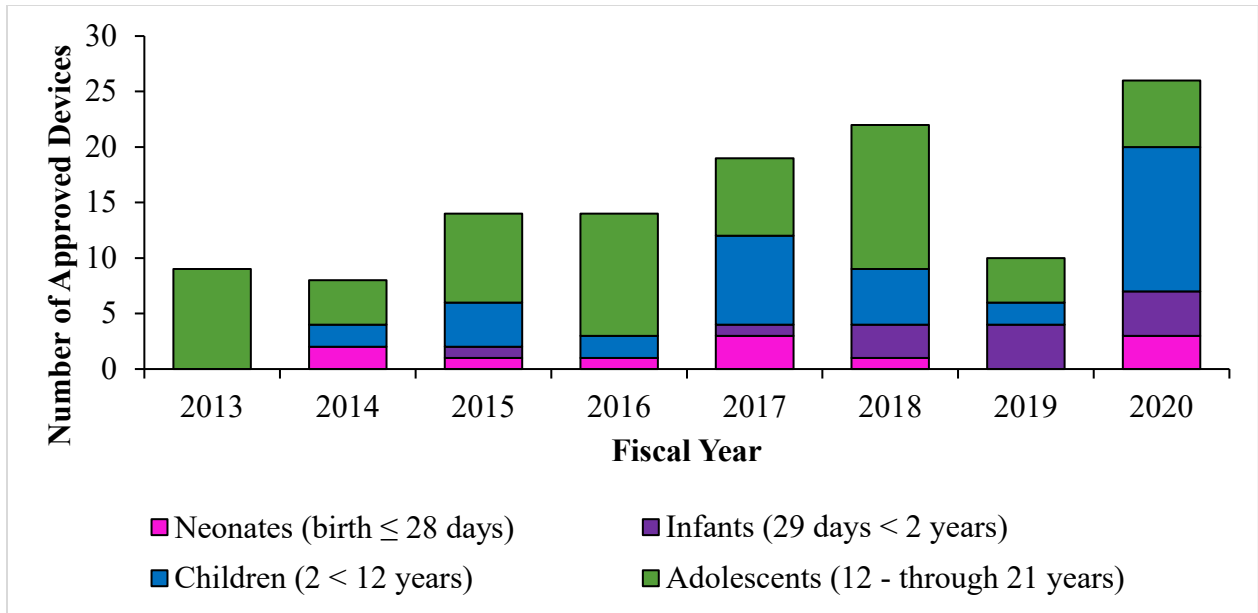


Figure 1B shows, by the age of each pediatric subpopulation, the PMA and HDE approvals for devices indicated for these subpopulations; these devices were reviewed by CDRH and CBER from FY 2008 to FY 2020. The PMA and HDE approvals are categorized by the youngest age for which there was an indication for use. In rare cases, a device may have only been used in a specific subpopulation.²⁶

Figure 1B. PMA and HDE Approvals by the Youngest Suggested Pediatric Subpopulation from FY 2013 to FY 2020.

²⁵ These numbers represent the combined PMA or HDE approvals by CDRH and CBER in FY 2017 and in FY 2010.

²⁶ See also Table 2 of Appendix B for a more detailed breakdown, by the age of each pediatric subpopulation, of PMA and HDE approvals for devices indicated for these subpopulations; these devices were reviewed by CDRH and CBER from FY 2013 to FY 2020.



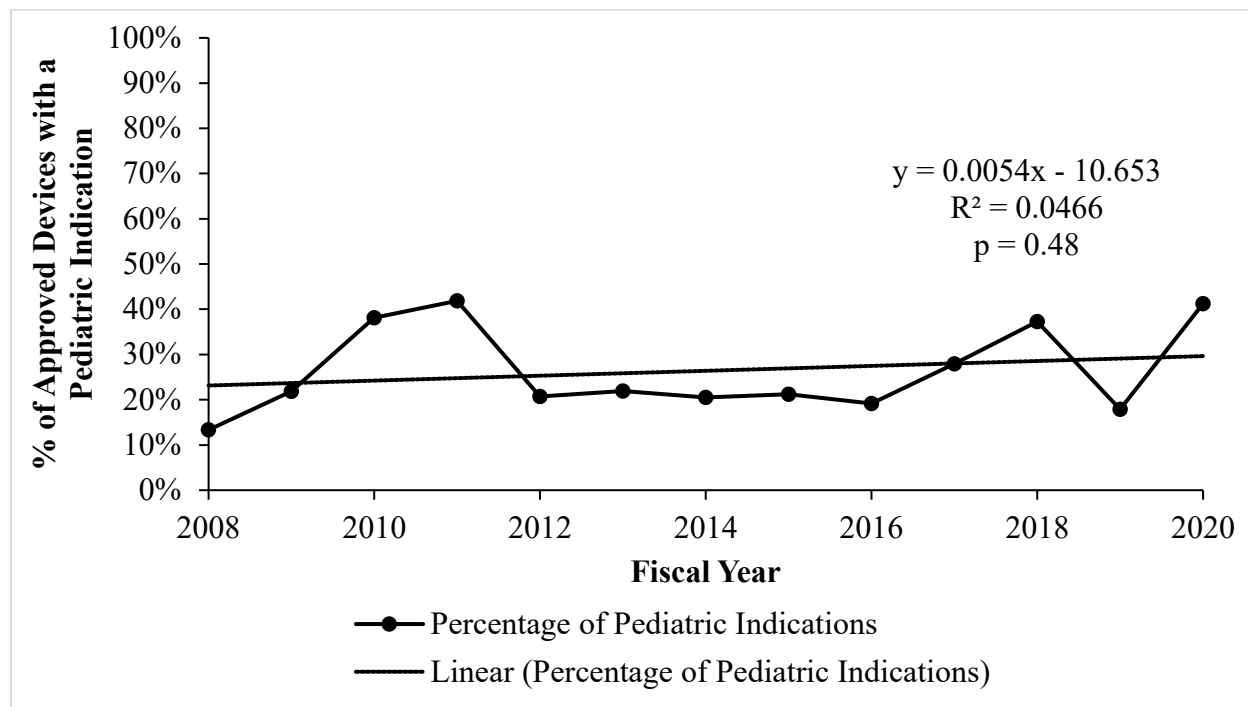
Appendix A includes a detailed summary of each of the FY 2019 and FY 2020 PMA and HDE approvals for devices that were indicated for use in a pediatric population or pediatric subpopulation.

Since FY 2008, the largest number (i.e., 26) of PMA and HDE approvals by CDRH and CBER for devices with an indication that included a pediatric population or subpopulation was in FY 2020.²⁷ As shown in Figure 2, the largest percentage of PMA and HDE approvals (i.e., 42%) for devices with an indication that included a pediatric population or subpopulation was in FY 2011.²⁸

²⁷ See Table 1 in Appendix B.

²⁸ See also Table 1 in Appendix B.

Figure 2. Percentage of PMA and HDEs Indicated for Use Within the Pediatric Population (Mean = 26% (170/644)).



On average for the last 13 fiscal years, only 26 percent of the total PMA and HDE approvals in each fiscal year have been for a device with an indication that includes a pediatric population or subpopulation. The percentage of pediatric indications increased between FY 2008 and FY 2011, but starting in FY 2012, the percentage of PMA and HDE approvals for devices with pediatric indications declined to 21 percent, only rising again to 28 percent in FY 2017 and 37 percent in FY 2018. The percentage of pediatric indications decreased to 18 percent in FY 2019 and increased to 41 percent in FY 2020.

IV. Conclusion

Since FY 2008, FDA has submitted reports to Congress providing information concerning FDA’s annual premarket approvals of devices that were indicated for pediatric use. This tenth such report, submitted under section 515A(a)(3) of the FD&C Act, includes data on the devices approved by CDRH and CBER, in FY 2019 and FY 2020, that had an indication for use in the pediatric population or its subpopulations. Based on the information summarized in this report, there have been limited changes since FY 2008 in FDA’s PMA or HDE approvals for devices indicated for use in a pediatric population or subpopulation. Since the passage of FDAAA, the number of devices approved for the pediatric population has generally increased; however, the

percentage of devices indicated for use in the pediatric population, out of the total number of devices approved each fiscal year, has remained relatively constant.²⁹

FDA is committed to continue working with the pediatric community to support the advancement, development, and availability of devices for use in the pediatric population. FDA takes seriously its responsibility to ensure that the devices on the market, including those for the pediatric population, demonstrate a reasonable assurance of safety and effectiveness. For the latest information on FDA's efforts related to pediatric devices refer, to FDA's Pediatric Medical Devices web page.³⁰

²⁹ See Table 1 in Appendix B.

³⁰ <https://www.fda.gov/medical-devices/products-and-medical-procedures/pediatric-medical-devices>.

Appendix A: The Devices Indicated for Use in Pediatric Populations Approved from FY 2019 to FY 2020

A. FY 2019 Approvals of, and Review Times for, PMA and HDEs for Devices Indicated for Use in Pediatric Populations

All devices included in this appendix are approved and labeled for use in a pediatric population.³¹ CDRH and CBER have provided the youngest suggested pediatric subpopulations, as designated under section 515A(c) of the FD&C Act, based on their analyses of publicly available information, such as the device's Summary of Safety and Effectiveness Data, Summary of Safety and Probable Benefit, and labeling, as well as additional factors, including but not limited to average pediatric anthropometric measurements and device dimensions.

FY 2019

Device Information

Powerheart® AED G3 Pro

The Powerheart® AED G3 Pro is indicated for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are:

- unresponsive,
- not breathing normally, and
- without pulse.

When the patient is a child or infant up to 8 years of age, or up to 55 lbs. (25kg), the device should be used with the Intellisense™ Defibrillation Pad – Pediatric. The therapy should not be delayed to determine the patient's exact age or weight.

The Powerheart® AED G3 Pro is intended to be used by personnel who have been trained in its operation.

Manufacturer	Zoll Medical Corporation
Number	P160034
Filing Date	08/04/2016
Approval Date	12/06/2018
Youngest Suggested Pediatric Subpopulation:	Infants
Exempt from User Fees because intended solely for pediatric use?	No

³¹ Additional information pertaining to these devices can be found in the Summary of Safety and Effectiveness Data or the Summary of Safety and Probable Benefit by searching the PMA or HDE number, respectively. The PMA and HDE approvals are listed in chronological order from the earliest approval date. In addition, please consult FDA's Medical Device Databases web (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases>) for more information.

FDA Days	180
Total Elapsed Days	854

Powerheart® AED G3, Powerheart® G3 Plus, and Powerheart® G5 AED

The Powerheart® AED G3 is indicated for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are:

- unresponsive,
- not breathing normally, and
- without pulse.

When the patient is a child or infant up to 8 years of age, or up to 55 lbs. (25kg), the device should be used with the Intellisense™ Defibrillation Pad – Pediatric. The therapy should not be delayed to determine the patient's exact age or weight.

The Powerheart® AED G3 is intended to be used by personnel who have been trained in its operation.

The Powerheart® AED G3 Plus is indicated for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are:

- unresponsive,
- not breathing normally, and
- without pulse.

When the patient is a child or infant up to 8 years of age, or up to 55 lbs. (25kg), the device should be used with the Intellisense™ Defibrillation Pad – Pediatric. The therapy should not be delayed to determine the patient's exact age or weight.

The Powerheart® AED G3 Plus is intended to be used by personnel who have been trained in its operation.

The Powerheart® AED G5 is indicated for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are:

- unresponsive,
- not breathing normally, and
- without pulse.

When a patient is a child up to 8 years of age, or up to 25kg (55 lbs.), the AED should be used with the Intellisense™ Defibrillation Pad – Pediatric. The therapy should not be delayed to determine the patient's exact age or weight.

The G5 Automated External Defibrillator (AED) is intended to be used by persons who have been trained in its operation.

When used with the optional Intellisense™ Defibrillation Pad – ICPR, the device offers CPR performance feedback to aid a trained rescuer by providing compression rate and depth performance

feedback through audio prompting. The Intellisense™ Defibrillation Pad – ICPR is indicated-for use on cardiac arrest patients 8 years of age or older, or who weigh more than 25 kg (55 lbs.).

Manufacturer	Zoll Medical Corporation
Number	P160033
Filing Date	08/08/2016
Approval Date	12/07/2018
Youngest Suggested Pediatric Subpopulation:	Infants
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	179
Total Elapsed Days	851

LIFEPAK® CR2 Defibrillator

The LIFEPAK® CR2 Defibrillator is indicated for use on patients 1 year of age and older in cardiopulmonary arrest. The patient must be unresponsive (unconscious), not breathing normally, and showing no signs of circulation (for example, no pulse, no coughing, or no movement).

The cprCOACH™ Feedback Technology in the LIFEPAK CR2 defibrillator is indicated for use on cardiopulmonary arrest patients and provides CPR guidance in accordance with the AHA Guidelines for patients 1 year of age and older.

The LIFEPAK® CR2 Defibrillator is intended for use by personnel who have been trained in its operation. Users should have received training in basic life support/AED, advanced life support, or a physician-authorized emergency medical response training program.

The LIFEPAK® CR2 Defibrillator is indicated to be used with the QUIK-STEP Pacing/ECG Defibrillation Electrodes and the LIFEPAK CR2 Lithium Battery.

Manufacturer	Physio-Control, Inc.
Number	P170018
Filing Date	08/09/2017
Approval Date	12/21/2018
Youngest Suggested Pediatric Subpopulation:	Infants (1 year and older)
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	240
Total Elapsed Days	499

Neuroform Atlas® Stent System

The Neuroform Atlas® Stent System is indicated for use with neurovascular embolization coils in the anterior circulation of the neurovasculature for the endovascular treatment of patients ≥ 18 years of age with saccular wide-necked (neck width ≥ 4 mm or a dome-to neck ratio of < 2) intracranial aneurysms arising from a parent vessel with a diameter of ≥ 2.0 mm and ≤ 4.5 mm.

Manufacturer	Stryker Neurovascular
Number	P180031
Filing Date	08/15/2018

Approval Date	05/16/2019
Youngest Suggested Pediatric Subpopulation:	Adolescent (18 years and older)
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	180
Total Elapsed Days	274

Eversense Continuous Glucose Monitoring System

The Eversense CGM System is indicated for continually measuring glucose levels in adults (age 18 and older) with diabetes for up to 90 days. The system is indicated for use to replace fingerstick blood glucose measurements for diabetes treatment decisions.

- The system is intended to:
- Provide real-time glucose readings.
 - Provide glucose trend information.
 - Provide alerts for the detection and prediction of episodes of low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia).

The system is a prescription device. Historical data from the system can be interpreted to aid in providing therapy adjustments. These adjustments should be based on patterns seen over time. The system is intended for single patient use.

Manufacturer	Senseonics, Inc.
Number	P160048/S006
Filing Date	12/11/2018
Approval Date	06/06/2019
Youngest Suggested Pediatric Subpopulation:	Adolescent (18 years and older)
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	125
Total Elapsed Days	177

HeartStart OnSite Defibrillator (Model M5066A) and HeartStart Home Defibrillator (Model 5068A)

- The HeartStart OnSite (Model M5066A) is indicated for use on potential victims of cardiac arrest with the following symptoms:
- Unconsciousness; and
 - Absence of normal breathing.

The HeartStart OnSite (Model M5066A) is indicated for adults over 55 pounds (25 kg). The OnSite is also indicated for infants/children under 55 lbs (25 kg) or 8 years old when used with the optional infant/child SMART pads (Model M5072A). If Infant/Child SMART pads are not available, or you are uncertain of the child’s age or weight, proceed with treatment using adult SMART pads (Model M5071A).

- The HeartStart Home (Model M5068A) is indicated for use on potential victims of cardiac arrest with the following symptoms:
- Unconsciousness; and
 - Absence of normal breathing.

The HeartStart Home (Model M5068A) is indicated for adults over 55 pounds (25 kg). The HeartStart Home is also indicated for infants and children under 55 lbs (25 kg) or 8 years old when used with the optional infant/child SMART pads (Model M5072A). If Infant/Child SMART pads are not available, or you are uncertain of the child's age or weight, proceed with treatment using adult SMART pads (Model M5071A).

Manufacturer	Philips Medical Systems, Inc.
Number	P160029
Filing Date	07/29/2016
Approval Date	06/06/2019
Youngest Suggested Pediatric Subpopulation:	Infants
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	189
Total Elapsed Days	1042

MED-EL Cochlear Implant System

The MED-EL Cochlear Implant System is indicated for evoking auditory sensations via electrical stimulation of the auditory pathways for individuals ages 5 years and above with single-sided deafness (SSD) or asymmetric hearing loss (AHL), where:

- SSD is defined as profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear.
- AHL is defined as a profound sensorineural hearing loss in one ear and mild to moderately severe sensorineural hearing loss in the other ear, with a difference of at least 15 dB in pure tone averages (PTAs) between ears.
- Profound hearing loss is defined as having a PTA of 90 dB HL or greater at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Normal hearing is defined as having a PTA of up to 15 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild hearing loss is defined as having a PTA of up to 30 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild to moderately severe hearing loss is defined as having a PTA ranging from 31 to up to 55 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz.

Individuals with SSD or AHL must obtain limited benefit from an appropriately fitted unilateral hearing aid in the ear to be implanted. For individuals ages 18 years-old and above, limited benefit from unilateral amplification is defined by test scores of five (5) percent correct or less on monosyllabic consonant-nucleus-consonant (CNC) words in quiet when tested in the ear to be implanted alone. For individuals between 5 and 18 years-old, insufficient functional access to sound in the ear to be implanted must be determined by aided speech perception test scores of five (5) percent or less on developmentally appropriate monosyllabic word lists when tested in the ear to be implanted alone.

Before implantation with a cochlear implant, individuals with SSD or AHL must have at least one (1) month experience wearing a Contra Lateral Routing of Signal (CROS) hearing aid or other relevant device and not show any subjective benefit.

Manufacturer	Med-EL Corp.
--------------	--------------

Number	P000025/S104
Filing Date	07/30/2018
Approval Date	07/19/2019
Youngest Suggested Pediatric Subpopulation:	Children (5 years and older)
Exempt from User Fees because intended solely for pediatric use?	No
FDA Day	179
Total Elapsed Days	354
The Tether™ - Vertebral Body Tethering System	
<p>The Tether™ - Vertebral Body Tethering System is indicated for skeletally immature patients that require surgical treatment to obtain and maintain correction of progressive idiopathic scoliosis, with a major Cobb angle of 30 to 65 degrees whose osseous structure is dimensionally adequate to accommodate screw fixation, as determined by radiographic imaging. Patients should have failed bracing and/or be intolerant to brace wear.</p>	
Manufacturer	Zimmer Biomet Spine, Inc.
Number	H190005
Filing Date	06/04/2019
Approval Date	08/16/2019
Youngest Suggested Pediatric Subpopulation:	Children (10 years and older)
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	73
Total Elapsed Days	73
Minimally Invasive Deformity Correction (MID-C) System	
<p>The MID-C System is indicated for use in patients with adolescent idiopathic scoliosis (AIS) for treatment of single curves classified as Lenke 1 (thoracic major curve) or Lenke 5 (thoracolumbar/lumbar major curve), having a Cobb angle of 45 to 60 degrees which reduces to less than or equal to 30 degrees on lateral side-bending radiographs, and thoracic kyphosis less than 55 degrees as measured from T5 to T12.</p>	
Manufacturer	ApiFix, Ltd.
Number	H170001
Filing Date	03/17/2017
Approval Date	08/23/2019
Youngest Suggested Pediatric Subpopulation:	Adolescents
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	203
FDA Elapsed Days	889
STAR S4 IR Excimer Laser System And IDESIGN Refractive Studio	
<p>The STAR S4 IR® Excimer Laser System and the iDESIGN® Refractive Studio is indicated for wavefront-guided photorefractive keratectomy (PRK) in patients:</p> <ul style="list-style-type: none"> • With myopia, with or without astigmatism, as measured by iDESIGN® Refractive Studio System with spherical equivalent up to -8.00 D, and cylinder up to -3.00 D. 	

- With agreement between manifest refraction (adjusted for optical infinity) and iDESIGN® Refractive Studio System refraction as follows:
 - Spherical Equivalent: Magnitude of the difference is less than 0.625 D.
 - Cylinder: Magnitude of the difference is less than or equal to 0.5 D.
- in patients 18 years of age or older,
- with refractive stability (a change of ≤ 1.0 D in manifest refraction spherical equivalent for a minimum of 12 months prior to surgery) and
- with wavefront capture diameter of at least 4 mm.

Manufacturer	AMO Manufacturing USA, LLC
Number	P930016/S057
Filing Date	01/02/2019
Approval Date	09/09/2019
Youngest Suggested Pediatric Subpopulation:	Adolescents (18 years and older)
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	180
Total Elapsed Days	250

B. FY 2020 Approvals of, and Review Times for, PMA and HDEs for Devices Indicated for Use in Pediatric Populations

FY 2020

Device Information

LIAISON XL MUREX HCV Ab; LIAISON XL MUREX Control HCV Ab

LIAISON XL MUREX HCV Ab assay

The LIAISON XL MUREX HCV Ab assay is an in vitro chemiluminescent immunoassay (CLIA) for the qualitative determination of specific antibodies to hepatitis C virus (anti-HCV) in human adult and pediatric (2 – 21 years) serum and plasma (lithium and sodium heparin, sodium citrate and di-potassium EDTA) samples including separator tubes, on the LIAISON XL Analyzer. It is intended to be used as an aid in the diagnosis of HCV infection. The assay may also be used as an aid in the diagnosis of HCV infection in pediatric subjects and in pregnant women. The test does not determine the state of infection or associated disease.

The assay is not intended for use in screening blood, plasma, or tissue donors.

LIAISON XL MUREX Control HCV Ab (negative and positive)

The LIAISON XL MUREX Control HCV Ab (negative and positive) is intended for use as assayed quality control samples to monitor the performance of the LIAISON XL MUREX HCV Ab assay. The performance characteristics of LIAISON XL MUREX Control HCV Ab have not been established for any other assays or instrument platforms different from LIAISON XL.

Manufacturer	DiaSorin, Inc.
Number	P190011
Filing Date	04/22/2019
Approval Date	10/18/2019
Youngest Suggested Pediatric Subpopulation:	Children (2 years and older)
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	179
Total Elapsed Days	179
MiSight 1 Day (Omafilcon A) Soft (Hydrophilic) Contact Lenses for Daily Wear	
<p>MiSight 1 Day (omafilcon A) Soft (Hydrophilic) Contact Lenses for Daily Wear are indicated for the correction of myopic ametropia and for slowing the progression of myopia in children with non-diseased eyes, who at the initiation of treatment are 8-12 years of age and have a refraction of -0.75 D to -4.00 D (spherical equivalent) with ≤ 0.75 diopters of astigmatism. The lens is to be discarded after each removal.</p>	
Manufacturer	CooperVision, Inc.
Number	P180035
Filing Date	09/04/2018
Approval Date	11/15/2019
Youngest Suggested Pediatric Subpopulation:	Children (8 years and older)
Exempt from User Fees because intended solely for pediatric use?	Yes
FDA Days	178
Total Elapsed Days	437
Tula® System	
<p>Tula System: The Tula® System is intended to create a myringotomy and insert a tympanostomy tube using the Tula Tube Delivery System in pediatric (aged 6 months and older) and adult patients indicated to receive tympanostomy tubes. The Tula System is used to deliver a tympanostomy tube under local anesthesia induced using the Tula Iontophoresis System and TYMBION™, a combination of an amide local anesthetic and an alpha- and beta-adrenergic agonist.</p> <p>TYMBION: TYMBION™, a combination of an amide local anesthetic and an alpha- and beta-adrenergic agonist, is indicated for the induction of local anesthesia of the tympanic membrane via iontophoresis using the Tula® Iontophoresis System in pediatric (aged 6 months and older) and adult patients undergoing tympanostomy tube placement using the Tula Tube Delivery System.</p>	
Manufacturer	Tusker Medical, Inc.
Number	P190016
Filing Date	06/03/2019
Approval Date	11/25/2019
Youngest Suggested Pediatric Subpopulation:	Infants (6 months and older)
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	240
Total Elapsed Days	499

LIAISON XL MUREX Anti-HBc, LIAISON MUREX Control Anti-HBc

The LIAISON XL MUREX Anti-HBc assay is an in vitro chemiluminescent immunoassay (CLIA) for the qualitative detection of IgG and IgM (total) antibodies to hepatitis B core antigen (anti-HBc) in human adult and pediatric (2 – 21 years) serum and plasma (lithium and sodium heparin, sodium citrate and K2 EDTA), including separator tubes, on the LIAISON XL Analyzer. Assay results in conjunction with other laboratory results and clinical information may be used as an aid in the diagnosis of hepatitis B virus (HBV) infection in patients with symptoms of hepatitis or who may be at risk for HBV infection.

The assay is not intended for use in screening blood, plasma, or tissue donors.

The LIAISON XL MUREX Control Anti-HBc (negative and positive) is intended for use as assayed quality control samples to monitor the performance of the LIAISON XL MUREX Anti-HBc assay. The performance characteristics of LIAISON XL MUREX Control Anti-HBc have not been established for any other assays or instrument platforms.

Manufacturer	DiaSorin, Inc.
Number	P180038
Filing Date	09/28/2018
Approval Date	01/02/2020
Youngest Suggested Pediatric Subpopulation:	Children (2 years and older)
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	169
Total Elapsed Days	461

Bulkamid Urethral Bulking System

Bulkamid Urethral Bulking System is indicated for urethral injection for the treatment of stress urinary incontinence (SUI) due to intrinsic sphincter deficiency (ISD) in adult women who have SUI or stress predominant mixed incontinence.

Manufacturer	Axonics Modulation Technologies, Inc.
Number	P170023
Filing Date	07/31/2017
Approval Date	01/28/2020
Youngest Suggested Pediatric Subpopulation:	Adolescent (18 years and older)
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	507
Total Elapsed Days	911

PyloPlus UBT System

The PyloPlus UBT system is intended for use in the qualitative detection of urease associated with H. pylori in the human stomach and is indicated as an aid in the initial diagnosis of H. pylori infection in adults 18 years old and older. The PyloPlus UBT system consists of the PyloPlus UBT Kit and the PyloPlus UBT analyzer. The analyzer is an infrared Spectrometer used for the measurement of the ratio

of $^{13}\text{CO}_2$ to $^{12}\text{CO}_2$ in breath samples. The PyloPlus UBT system is for use by trained health care professionals as prescribed by a physician.

Manufacturer	ARJ Medical, Inc.
Number	P170022
Filing Date	10/23/2017
Approval Date	02/18/2020
Youngest Suggested Pediatric Subpopulation:	Adolescent (18 years and older)
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	191
Total Elapsed Days	848

LIAISON® XL MUREX Anti-HBs, LIAISON® XL MUREX Control Anti-HBs, and LIAISON® XL MUREX Anti-HBs Verifiers

The LIAISON XL MUREX Anti-HBs is an in vitro chemiluminescent immunoassay (CLIA) for the qualitative and quantitative determination of antibody to hepatitis B surface antigen (anti-HBs) in human adult and pediatric (2 – 21 years) serum and plasma (lithium and sodium heparin and K2 EDTA) including separator tubes, on the LIAISON XL Analyzer. Assay results in conjunction with other hepatitis B virus (HBV) serological markers and clinical information may be used as an aid in the diagnosis of HBV infection in patients with symptoms of hepatitis or who may be at risk for HBV infection. The assay results may be used as an aid in the determination of susceptibility to HBV infection in individuals prior to or following HBV vaccination or where vaccination status is unknown.

The assay is not approved for use in screening blood, plasma or tissue donors.

The LIAISON XL MUREX Control Anti-HBs (negative and positive) is intended for use as assayed quality control samples to monitor the performance of the LIAISON XL MUREX Anti-HBs assay. The performance characteristics of LIAISON XL MUREX Control Anti-HBs have not been established for any other assays or instrument platforms.

The LIAISON XL MUREX Anti-HBs Verifiers (level 1, 2, 3, and level 4) are assayed quality control materials intended for the quantitative verification of calibration and reportable range of the LIAISON XL MUREX Anti-HBs assay. The performance characteristics of LIAISON XL MUREX Anti-HBs Verifiers have not been established in connection with any other assay or instrument platforms.

Manufacturer	DiaSorin, Inc.
Number	P180039
Filing Date	09/28/2018
Approval Date	02/21/2020
Youngest Suggested Pediatric Subpopulation:	Children (2 years and older)
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	175
Total Elapsed Days	511

NUCLEUS 24 COCHLEAR IMPLANT SYSTEM

Adults

The Nucleus 24 Cochlear Implant System is intended for individuals 18 years of age or older who have bilateral, pre, peri or postlinguistic sensorineural hearing impairment and obtain limited benefit from appropriate binaural hearing aids.

These individuals typically have moderate to profound hearing loss in the low frequencies and profound (≥ 90 dB HL) hearing loss in the mid to high speech frequencies. Limited benefit from amplification is defined by test scores of 50% correct or less in the ear to be implanted (60% or less in the best-aided listening condition) on tape-recorded tests of open set sentence recognition.

Children

The Nucleus 24 cochlear implant system is intended for use in children 9 to 24 months of age who have bilateral profound sensorineural deafness and demonstrate limited benefit from appropriate binaural hearing aids. Children two years of age or older may demonstrate severe to profound hearing loss bilaterally. In younger children, limited benefit is defined as lack of progress in the development of simple auditory skills in conjunction with appropriate amplification and participation in intensive aural habilitation over a three to six-month period. It is recommended that limited benefit be quantified on a measure such as the Meaningful Auditory Integration Scale or the Early Speech Perception test. In older children, limited benefit is defined as $\leq 30\%$ correct on the open set Multisyllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood Test (LNT), depending upon the child's cognitive and linguistic skills. A three to six-month hearing aid trial is recommended for children without previous aided experience.

Manufacturer	Cochlear Americas
Number	P970051/S172
Filing Date	06/20/2019
Approval Date	03/17/2020
Youngest Suggested Pediatric Subpopulation:	Infants (9 months and older)
Exempt from User Fees because intended solely for pediatric use?	Yes
FDA Day	180
Total Elapsed Days	271

Alinity M HCV

The Alinity m HCV assay is an in vitro reverse transcription-polymerase chain reaction (RT-PCR) assay for both the detection and quantitation of hepatitis C virus (HCV) RNA, in human plasma (EDTA, Acid Citrate Dextrose) or serum, from HCV antibody positive individuals. The assay is intended for use as an aid in the diagnosis of active HCV infection in individuals with antibody evidence of HCV infection, and to aid in the management of patients with known active HCV infection, including SVR determination. The results from the Alinity m HCV assay must be interpreted within the context of all relevant clinical and laboratory findings.

The Alinity m HCV assay is not intended to be used in screening blood, plasma, serum, tissue or tissue donors for HCV.

Manufacturer	Abbott Molecular, Inc.
Number	P190025
Filing Date	09/30/2019

Approval Date	03/23/2020
Youngest Suggested Pediatric Subpopulation:	Children
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	175
Total Elapsed Days	175
Elecsys HIV Duo	
<p>The test is intended to be used as an aid in diagnosis of HIV-1/HIV-2 infection. Detection of HIV-1 or HIV-2 nucleic acid is indicative of HIV-1 or HIV-2 infection, respectively. The presence of HIV-1 or HIV-2 nucleic acid in the plasma or serum of individuals without antibodies to HIV-1 or HIV-2 is indicative of acute or primary infection.</p>	
Manufacturer	Roche Diagnostics Operations, Inc.
Number	BP190403
Filing Date	09/27/2019
Approval Date	04/10/2020
Youngest Suggested Pediatric Subpopulation:	Children
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	140
Total Elapsed Days	196
Inspire Upper Airway Stimulation	
<p>Inspire® Upper Airway Stimulation (UAS) is used to treat a subset of patients with moderate to severe obstructive sleep apnea (OSA) (apnea-hypopnea index [AHI] of greater than or equal to 15 and less than or equal to 65). Inspire® UAS is used in adult patients 22 years of age and older who have been confirmed to fail or cannot tolerate positive airway pressure (PAP) treatments (such as continuous positive airway pressure [CPAP] or bi-level positive airway pressure [BPAP] machines) and who do not have a complete concentric collapse at the soft palate level.</p>	
<p>PAP failure is defined as an inability to eliminate OSA (AHI of greater than 15 despite PAP usage), and PAP intolerance is defined as:</p>	
<ol style="list-style-type: none"> (1) Inability to use PAP (greater than 5 nights per week of usage; usage defined as greater than 4 hours of use per night), or (2) Unwillingness to use PAP (for example, a patient returns the PAP system after attempting to use it). 	
<p>Inspire® UAS is also indicated for use in patients between the ages of 18 and 21 with moderate to severe OSA ($15 \leq \text{AHI} \leq 65$) who:</p>	
<ul style="list-style-type: none"> • Do not have complete concentric collapse at the soft palate level • Are contraindicated for, or not effectively treated by, adenotonsillectomy • Have been confirmed to fail, or cannot tolerate, PAP therapy despite attempts to improve compliance • Have followed standard of care in considering all other alternative/adjunct therapies 	
Manufacturer	INSPIRE MEDICAL SYSTEMS
Number	P130008/S039
Filing Date	05/03/2019

Approval Date	04/14/2020
Youngest Suggested Pediatric Subpopulation:	Adolescents (18 years and older)
Exempt from User Fees because intended solely for pediatric use?	Yes
FDA Days	180
Total Elapsed Days	347
HeartStart FRx Defibrillator	
<p>The HeartStart FRx Defibrillator (Model 861304) is indicated for use on potential victims of sudden cardiac arrest (SCA) with the following symptoms:</p> <ul style="list-style-type: none"> • Unconsciousness, and • Absence of normal breathing <p>The HeartStart FRx (Model 861304) is indicated for adults over 55 pounds (25 kg). The Model 861304 is also indicated for infants and children under 55 pounds (25 kg) or 0- 8 years old when used with the optional Infant/Child Key (Model 989803139311). If the Infant/Child Key is not available, or you are uncertain of the child’s age or weight, proceed using adult treatment without the infant/child key.</p>	
Manufacturer	Philips Medical Systems
Number	P180028
Filing Date	08/03/2018
Approval Date	05/11/2020
Youngest Suggested Pediatric Subpopulation:	Neonates
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	92
Total Elapsed Days	647
Philips HeartStart FR3 Defibrillator	
<p>The models 861388 and 861389 are indicated for use by trained responders to treat ventricular fibrillation (VF), the most common cause of sudden cardiac arrest (SCA), and pulseless ventricular tachycardias (VTs). The models 861388 and 861389 are used with the SmartPads III or DP defibrillator pads applied to potential victims of SCA with the following symptoms:</p> <ul style="list-style-type: none"> • Unconsciousness • Absence of normal breathing • Absence of pulse or signs of circulation <p>The models 861388 and 861389 are indicated for adults and children over 55 pounds (25 kg) or greater than 8 years old. The models 861388 and 861389 are also indicated for children under 55 pounds (25 kg) or 0-8 years old when used with the optional Infant/Child Key. If the Infant/Child Key is not available, or you are uncertain of the child’s age or weight, do not delay treatment.</p>	
Manufacturer	Philips Medical System
Number	P160028
Filing Date	07/29/2016
Approval Date	05/11/2020
Youngest Suggested Pediatric Subpopulation:	Neonates
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	184

Total Elapsed Days	1382
FoundationOne CDx (F1CDx)	
<p>FoundationOne®CDx (F1CDx) is a qualitative next generation sequencing based in vitro diagnostic test that uses targeted high throughput hybridization-based capture technology for detection of substitutions, insertion and deletion alterations (indels) and copy number alterations (CNAs) in 324 genes and select gene rearrangements, as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB) using DNA isolated from formalin-fixed paraffin embedded (FFPE) tumor tissue specimens. The test is intended as a companion diagnostic to identify patients who may benefit from treatment with the targeted therapies listed in Table 1 in accordance with the approved therapeutic product labeling. Additionally, F1CDx is intended to provide tumor mutation profiling to be used by qualified health care professionals in accordance with professional guidelines in oncology for cancer patients with solid malignant neoplasms. Genomic findings other than those listed in Table 1 are not prescriptive or conclusive for labeled use of any specific therapeutic product.</p>	
Manufacturer	Foundation Medicine, Inc.
Number	P170019/S016
Filing Date	04/01/2020
Approval Date	06/16/2020
Youngest Suggested Pediatric Subpopulation:	Infants
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	76
Total Elapsed Days	76
Neuroform Atlas® Stent System	
<p>The Neuroform Atlas Stent System is indicated for use with neurovascular embolization coils in the anterior and posterior circulation of the neurovasculature for the endovascular treatment of patients \geq 18 years of age with saccular wide-necked (neck width \geq 4 mm or a dome-to-neck ratio of $<$ 2) intracranial aneurysms arising from a parent vessel with a diameter of \geq 2.0 mm and \leq 4.5 mm.</p>	
Manufacturer	Stryker Neurovascular
Number	P180031/S001
Filing Date	07/22/2019
Approval Date	07/30/2020
Youngest Suggested Pediatric Subpopulation:	Adolescents (18 years and older)
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	180
Total Elapsed Days	374
Cardinal Health Multifunctional Defibrillation Electrode	
<p>The Multi-Function Defibrillation Electrodes are intended to transfer energy from a cardiac defibrillator or pacer to the body of a patient for the purpose of defibrillation, synchronized cardioversion, pacing, or for ECG monitoring.</p>	

The Kendall™ and Medi-Trace™ Cadence Adult Multi-Function Defibrillation Electrodes with connectors intended for use with Physio-Control LIFEPAK (LP) defibrillators are compatible with Physio-Control / Stryker LP 15, LP 20, LP 20E, LP 1000, LP CR Plus, and LP Express defibrillators with the exception of the Kendall™ 1010P Adult Multi-Function Defibrillation Electrode, which is compatible with PhysioControl LP 20 and LP 20e defibrillators and the Physio-Control FAST-PATCH® cable.

The Medi-Trace™ Cadence Pediatric Multi-Function Defibrillation Electrodes with connectors intended for use with Physio-Control / Stryker defibrillators are compatible with Physio-Control LP 15, LP 20, and LP 20e defibrillators.

The Kendall™ and Medi-Trace™ Cadence Adult Multi-Function Defibrillation Electrodes with connectors intended for use with ZOLL defibrillators are compatible with ZOLL R Series BLS, R Series Plus, R Series ALS, X Series, and Propaq MD defibrillators.

The Physio-Control/Stryker QUIK-COMBO Adult pacing/defibrillation/ECG electrodes and QUIK-COMBO Pediatric pacing/defibrillation/ECG electrodes are compatible with LP 15, LP 20, and LP 20e defibrillators. The Physio-Control/Stryker QUIK-COMBO pacing/defibrillation/ECG electrode with REDI-PAK Preconnect system is compatible with LP 15, LP 20, LP 20e, LP 1000, LP CR Plus, and LP EXPRESS defibrillators.

Manufacturer	Cardinal Health
Number	P190007
Filing Date	03/25/2019
Approval Date	08/07/2020
Youngest Suggested Pediatric Subpopulation:	Infants
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	180
Total Elapsed Days	374

Cobas® HIV-1/HIV-2 Qualitative

The test is intended to be used as an aid in diagnosis of HIV-1/HIV-2 infection. Detection of HIV-1 or HIV-2 nucleic acid is indicative of HIV-1 or HIV-2 infection, respectively. The presence of HIV-1 or HIV-2 nucleic acid in the plasma or serum of individuals without antibodies to HIV-1 or HIV-2 is indicative of acute or primary infection. The Cobas® HIV-1/HIV-2 Qualitative may also be used as an additional test to confirm the presence of HIV-1 or HIV-2 infection in an individual with specimens reactive for HIV-1 or HIV-2 antibodies or antigens. The assay may also be used as an aid in the diagnosis of infection with HIV-1 and/or HIV-2 in pediatric subjects and pregnant women.

Manufacturer	Roche Molecular Systems, Inc.
Number	BP190360
Filing Date	06/13/2019
Approval Date	08/12/2020
Youngest Suggested Pediatric Subpopulation:	Neonates
Exempt from User Fees because intended solely for pediatric use?	No

FDA Days	176
Total Elapsed Days	426
FoundationOne Liquid CDx (F1 Liquid CDx)	
<p>FoundationOne® Liquid CDx is a qualitative next generation sequencing based in vitro diagnostic test that uses targeted high throughput hybridization-based capture technology to detect and report substitutions, insertions and deletions (indels) in 311 genes, including rearrangements and copy number losses only in BRCA1 and BRCA2. FoundationOne® Liquid CDx utilizes circulating cell-free DNA (cfDNA) isolated from plasma derived from anti-coagulated peripheral whole blood of cancer patients collected in FoundationOne® Liquid CDx cfDNA blood collection tubes included in the FoundationOne® Liquid CDx Blood Sample Collection Kit. The test is intended to be used as a companion diagnostic to identify patients who may benefit from treatment with the targeted therapies listed in Table 1 in accordance with the approved therapeutic product labeling. Additionally, FoundationOne® Liquid CDx is intended to provide tumor mutation profiling for substitutions and indels to be used by qualified health care professionals in accordance with professional guidelines in oncology for patients with solid malignant neoplasms.</p>	
Manufacturer	Foundation Medicine, Inc.
Number	P190032
Filing Date	12/26/2019
Approval Date	08/26/2020
Youngest Suggested Pediatric Subpopulation:	Adolescents
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	180
Total Elapsed Days	244
Alinity M HBV	
<p>The Alinity m HBV assay is an in vitro polymerase chain reaction (PCR) assay for use with the automated Alinity m System to quantitate Hepatitis B Virus (HBV) DNA in human plasma or serum. The Alinity m HBV assay is intended for use as an aid in the management of patients with chronic HBV infection undergoing anti-viral therapy. The assay can be used to measure HBV DNA levels at baseline and during treatment to aid in assessing response to treatment. The results from the Alinity m HBV assay must be interpreted within the context of all relevant clinical and laboratory findings.</p> <p>This assay is not intended to be used for screening donors of blood, blood products, or cell, tissue, and cellular and tissue-based products (HCT/Ps) or as a diagnostic test to confirm the presence of HBV infection.</p>	
Manufacturer	Abbott Molecular, Inc.
Number	P200013
Filing Date	03/02/2020
Approval Date	08/29/2020
Youngest Suggested Pediatric Subpopulation:	Children
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	180

Total Elapsed Days

180

LIAISON® XL MUREX HBsAg Qual, LIAISON® MUREX Control HBsAg, and LIAISON® XL MUREX HBsAg Confirmatory Test

LIAISON XL MUREX HBsAg Qual

The LIAISON® XL MUREX HBsAg Qual assay is an in vitro chemiluminescent immunoassay (CLIA) for the qualitative detection of hepatitis B surface antigen (HBsAg) in human adult and pediatric (2 to 21 years) serum and plasma (lithium and sodium heparin, sodium citrate and potassium EDTA), including separator tubes, on the LIAISON® XL Analyzer. Assay results, in conjunction with other hepatitis B virus (HBV) serological and clinical information, may be used as an aid in the diagnosis of HBV infection in patients with symptoms of hepatitis or who may be at risk for HBV infection. The assay may also be used to screen for HBV infection in pregnant women to identify neonates who are at risk for acquiring hepatitis B during the perinatal period.

This assay is not approved for use in screening blood, plasma or tissue donors.

LIAISON XL MUREX Control HBsAg Qual

The LIAISON® XL MUREX Control HBsAg Qual (negative and positive) is intended for use as assayed quality control samples to monitor the performance of the LIAISON® XL MUREX HBsAg Qual assay. The performance characteristics of LIAISON® controls have not been established for any other assays or instrument platforms difference from LIAISON® XL.

Manufacturer	DiaSorin, Inc.
Number	P190017
Filing Date	06/28/2019
Approval Date	08/29/2020
Youngest Suggested Pediatric Subpopulation:	Children (2 years and older)
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	266
FDA Elapsed Days	428

LIAISON® XL MUREX Anti-HBe, LIAISON® XL MUREX Control Anti-HBe

LIAISON XL MUREX Anti-HBe

The LIAISON® XL MUREX Anti-HBe assay is an in vitro chemiluminescent immunoassay (CLIA) for the qualitative detection of total antibodies to hepatitis B e antigen (anti-HBe) in human adult and pediatric (2 to 21 years) serum and plasma (lithium and sodium heparin, sodium citrate and K2 EDTA), including separator tubes, on the LIAISON® XL Analyzer. Assay results, in conjunction with other laboratory results and clinical information may be used as an aid in the diagnosis of hepatitis B virus (HBV) infection in patients with symptoms of hepatitis or who may be at risk for hepatitis B virus (HBV) infection.

This assay is not approved for use in screening blood, plasma or tissue donors.

LIAISON XL MUREX Control Anti-HBe

The LIAISON® XL MUREX Control Anti-HBe (negative and positive) is intended for use as assayed quality control samples to monitor the performance of the LIAISON® XL MUREX Anti-HBe assay. The performance characteristics of LIAISON® XL MUREX Control Anti-HBe have not been established for any other assays or instrument platforms different from LIAISON®XL Analyzer.

Manufacturer	DiaSorin, Inc.
Number	P180049
Filing Date	12/19/2018
Approval Date	08/29/2020
Youngest Suggested Pediatric Subpopulation:	Children (2 years and older)
Exempt from User Fees because intended solely for pediatric use?	No
FDA Day	296
Total Elapsed Day	619

LIAISON® XL MUREX HBeAg, LIAISON® XL MUREX Control HBeAg

LIAISON® XL MUREX HBeAg

The LIAISON® XL MUREX HBeAg assay is an in vitro chemiluminescent immunoassay (CLIA) for the qualitative detection of hepatitis B virus (HBV) e antigen (HBeAg) in human adult and pediatric (2-21 years) serum and plasma (lithium and sodium heparin, sodium citrate and K2 EDTA), including separator tubes, on the LIAISON® XL Analyzer. Assay results in conjunction with other laboratory results and clinical information may be used as an aid in the diagnosis of hepatitis B virus (HBV) infection in patients with symptoms of hepatitis or who may be at risk for hepatitis B virus (HBV) infection.

This assay is not approved for use in screening blood, plasma or tissue donors.

LIAISON® XL MUREX Control HBeAg

The LIAISON® XL MUREX Control HBeAg (negative and positive) is intended for use as assayed quality control samples to monitor the performance of the LIAISON® XL MUREX HBeAg assay. The performance characteristics of LIAISON® XL MUREX Control HBeAg have not been established for any other assays or instrument platforms.

Manufacturer	DiaSorin, Inc.
Number	P180048
Filing Date	12/14/2018
Approval Date	08/29/2020
Youngest Suggested Pediatric Subpopulation:	Children (2 years and older)
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	299
FDA Elapsed Days	624

LIAISON® XL MUREX HBc IgM, LIAISON® XL MUREX Control HBc IgM

LIAISON® XL MUREX Anti-HBc IgM

The LIAISON® XL MUREX HBc IgM assay is an in vitro chemiluminescent immunoassay (CLIA) for the qualitative detection of IgM anti-bodies to hepatitis B virus core antigen (HBc IgM) in human adult and pediatric (2 to 21 years) serum and plasma (lithium and sodium heparin, sodium citrate and

K2 EDTA), including separator tubes, on the LIAISON® XL Analyzer. Assay results, in conjunction with other hepatitis B virus (HBV) serological markers and clinical information may be used as an aid in the diagnosis of HBV infection in patients with symptoms of hepatitis or who may be at risk for HBV infection. The presence of anti-HBc IgM is indicative of acute or recent HBV infection.

This assay is not approved for use in screening blood, plasma or tissue donors.

LIAISON® XL MUREX Control Anti-HBc IgM

The LIAISON® XL MUREX Control HBc IgM (negative and positive) is intended for use as assayed quality control samples to monitor the performance of the LIAISON® XL MUREX HBc IgM assay. The performance characteristics of LIAISON® XL MUREX Control HBc IgM have not been established for any other assays or instrument platforms.

Manufacturer	DiaSorin, Inc.
Number	P180045
Filing Date	12/06/2018
Approval Date	08/29/2020
Youngest Suggested Pediatric Subpopulation:	Children (2 years and older)
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	288
Total Elapsed Days	632

Edwards SAPIEN 3 Transcatheter Heart Valve System with Edwards Commander Delivery System

The Edwards SAPIEN 3 Transcatheter Heart Valve (THV) System with Edwards Commander Delivery System is indicated for use in the management of pediatric and adult patients who have a clinical indication for intervention on a dysfunctional right ventricular outflow tract (RVOT) conduit or surgical bioprosthetic valve in the pulmonic position with \geq moderate regurgitation and/or a mean RVOT gradient of \geq 35 mmHg.

Manufacturer	Edwards Lifesciences, LLC
Number	P200015
Filing Date	03/09/2020
Approval Date	08/31/2020
Youngest Suggested Pediatric Subpopulation:	Children (5 years and older)
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	175
Total Elapsed Days	175

MiniMed 770G System

The MiniMed 770G system is intended for continuous delivery of basal insulin (at user selectable rates) and administration of insulin boluses (in user selectable amounts) for the management of type 1 diabetes mellitus in persons two years of age and older requiring insulin as well as for the continuous monitoring and trending of glucose levels in the fluid under the skin. The MiniMed 770G System includes SmartGuard technology, which can be programmed to automatically adjust delivery of basal insulin based on continuous glucose monitoring (CGM) sensor glucose values and can suspend

delivery of insulin when the sensor glucose value falls below or is predicted to fall below predefined threshold values.

Manufacturer	Medtronic MiniMed, Inc.
Number	P160017/S076
Filing Date	11/01/2019
Approval Date	08/31/2020
Youngest Suggested Pediatric Subpopulation:	Children (2 years and older)
Exempt from User Fees because intended solely for pediatric use?	Yes
FDA Days	180
Total Elapsed Days	304

THERMOCOOL SMARTTOUCH® SF Catheter

The Biosense Webster THERMOCOOL SMARTTOUCH® SF Navigation Catheter and related accessory devices are indicated for catheter-based cardiac electrophysiological mapping (stimulating and recording) and, when used with a compatible RF generator, for the treatment of:

- Type I atrial flutter in patients age 18 or older.
- Drug refractory recurrent symptomatic paroxysmal atrial fibrillation, when used with compatible three-dimensional electroanatomic mapping systems.
- Drug refractory recurrent symptomatic persistent atrial fibrillation (defined as continuous atrial fibrillation that is sustained beyond 7 days but less than 1 year), refractory or intolerant to at least one Class I or III antiarrhythmic medicine, when used with compatible three-dimensional electroanatomic mapping systems.

The THERMOCOOL SMARTTOUCH® SF Navigation Catheter provides a real-time measurement of contact force between the catheter tip and heart wall, as well as location information when used with CARTO® 3 Navigation System.

Manufacturer	Biosense Webster, Inc.
Number	P030031/S100
Filing Date	02/27/2020
Approval Date	09/30/2020
Youngest Suggested Pediatric Subpopulation:	Adolescent (18 years and older)
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	180
Total Elapsed Days	216

Appendix B: PMA and HDE Approvals for Devices with a Pediatric Indication from FY 2008 to FY 2020 by CDRH and CBER

Table 1. Total PMA and HDE Approvals and PMA and HDE Approvals for Devices with a Pediatric Indication from FY 2008 to FY 2020 (per Center).

Fiscal Year	Approved PMA and HDE Devices by Center		Total Approved PMA and HDE Devices	Approved Pediatric PMA and HDE Devices by Center		Total Approved Pediatric PMA and HDE Devices
	CDRH	CBER		CDRH	CBER	
2008	29	1	30	4	0	4 (13%)
2009	31	1	32	7	0	7 (22%)
2010	20	1	21	7	1	8 (38%)
2011	41	2	43	17	1	18 (42%)
2012	52	1	53	11	0	11 (21%)
2013	39	2	41	8	1	9 (22%)
2014	37	2	39	8	0	8 (21%)
2015	61	5	66	11	3	14 (21%)
2016	71	2	73	13	1	14 (19%)
2017	66	2	68	18	1	19 (28%)
2018	57	2	59	20	2	22 (37%)
2019	55	1	56	10	0	10 (18%)
2020	60	3	63	24	2	26 (41%)

In Table 2, the devices were categorized by the youngest age for which there was an indication for use.

Table 2. PMA and HDE Approvals Indicated for Pediatric Subpopulations by Age from FY 2013 to FY 2020.

Pediatric Subpopulation	PMA	HDE	Total
FY 2013			
Neonates (birth - 28 days)	0	0	0
Infants (29 days to <2 years)	0	0	0
Children (2 - 12 years)	0	0	0
Adolescents (12 - 21 years)	9	0	9
FY 2014			
Neonates (birth - 28 days)	1	1	2
Infants (29 days to <2 years)	0	0	0
Children (2 - 12 years)	1	1	2
Adolescents (12 - 21 years)	4	0	4
FY 2015			
Neonates (birth - 28 days)	1	0	1
Infants (29 days to <2 years)	1	0	1
Children (2 - 12 years)	4	0	4
Adolescents (12 - 21 years)	7	1	8
FY 2016			
Neonates (birth - 28 days)	0	1	1
Infants (29 days to <2 years)	0	0	0
Children (2 - 12 years)	2	0	2
Adolescents (12 - 21 years)	11	0	11
FY 2017			
Neonates (birth - 28 days)	2	1	3
Infants (29 days to <2 years)	1	0	1
Children (2 - 12 years)	8	0	8
Adolescents (12 - 21 years)	6	1	7
FY 2018			
Neonates (birth - 28 days)	1	0	1
Infants (29 days to <2 years)	3	0	3
Children (2 - 12 years)	4	1	5
Adolescents (12 - 21 years)	13	0	13
FY 2019			
Neonates (birth - 28 days)	0	0	0
Infants (29 days to <2 years)	4	0	4
Children (2 - 12 years)	1	1	2
Adolescents (12 - 21 years)	3	1	4
FY 2020			
Neonates (birth - 28 days)	3	0	3

Infants (29 days to <2 years)	4	0	4
Children (2 - 12 years)	13	0	13
Adolescents (12 - 21 years)	6	0	6

This report was prepared by FDA's Center for Devices and Radiological Health. For more information, please contact:

U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

This report is available on FDA's home page at <https://www.fda.gov/>.

