



**U.S. FOOD & DRUG
ADMINISTRATION**

REPORT TO CONGRESS

Premarket Approval of Pediatric Uses of Devices

FY 2018

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 that provides information concerning the premarket approvals of devices labeled¹ for pediatric use, among other requirements. This ninth 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 provides information from FDA's Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER), and it reflects device approvals during fiscal year (FY) 2018 (October 1, 2017, through September 30, 2018).³

In particular, this report highlights the following information for premarket approvals in FY 2018 as required under the FD&C Act:⁴

- FDA approved 57 original and panel-track supplement premarket approval (PMAs) applications and two humanitarian device exemption (HDE) applications for devices, for a total of 59 approvals.
- Of those 59 device approvals, FDA approved 21 PMAs and one HDE indicated for use in a pediatric population or subpopulation.^{5,6}
- Of the remaining 37 device approvals, 36 PMAs and one HDE were indicated for use in adults. Of these 37, 31 (or 84 percent) 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.⁷

¹ See FD&C Act 201(k) 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 *pediatric subpopulations* by reference to section 520(m)(6)(E)(ii) of the FD&C Act, which means one of the following subpopulations: neonates, infants, children, and adolescents.

³ In this report, FDA includes statistical data on the pediatric use of devices approved by CDRH and CBER.

⁴ Public Laws 110-85 and 115-52.

⁵ More information about these FY2018 pediatric device approvals, including these devices' review times and the pediatric population for which they were indicated at the time of initial approval, appears in Appendix A of this report.

⁶ See sections 515A(a)(3)(C) and 515A(a)(3)(D) of the FD&C Act.

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

- Four PMAs relied on data from adults, which supported FDA’s determination of a reasonable assurance of safety and effectiveness in pediatric patients.⁸
- For one device approval, FDA relied on data from one pediatric subpopulation to support a determination of a reasonable assurance of safety and effectiveness in another pediatric subpopulation.⁹
- Out of the 57 PMA approvals, no PMAs indicated solely for a pediatric population were exempted from user fees.¹⁰
- The median time to review the 21 PMAs indicated for use in a pediatric population or subpopulation was 180 FDA Days¹¹ and 359 total elapsed days until approval. The median time to review the HDE indicated for use in a pediatric population or subpopulation was 216 FDA Days and 277 total elapsed days until approval.¹²
- Based on a review of data available to FDA, such as the PMA and HDE periodic reports received in FY 2018, there were 18 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.¹³
- As required under section 502(d) of the FDA Reauthorization Act of 2017 (FDARA),¹⁴ FDA held a public meeting from August 13 to 14, 2018, on pediatric medical device

⁸ See section 515A(a)(3)(G) of the FD&C Act.

⁹ See section 515A(a)(3)(H) of the FD&C Act.

¹⁰ See section 515A(a)(3)(E) of the FD&C Act. Note that HDE applications are exempt from user fees under section 738(a)(2)(B)(i) of the FD&C Act.

¹¹ 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>.

¹² See section 515A(a)(3)(F) of the FD&C Act.

¹³ See section 515A(a)(3)(B) of the FD&C Act. PMAs are subject to periodic reporting requirements set forth in the PMA approval order (21 CFR 814.82(a), 21 CFR 814.84(b)). Similarly, HDEs must submit periodic reports in accordance with the HDE approval order under 21 CFR 814.126(b).

¹⁴ Public Law 115-52.

development.¹⁵ Section IV of this report provides a summary of and responses to recommendations raised in the meeting.

¹⁵ See <http://wayback.archive-it.org/7993/20180124135152/https://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/default.htm>.

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I. Introduction

The Food and Drug Administration Amendments Act of 2007 (FDAAA)¹⁶ 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 submit certain device applications for which approval is sought and, if readily available, to include a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure and the number of affected pediatric patients.¹⁷ FDAAA also added section 515A(a)(3) requiring the Food and Drug Administration (FDA or Agency) to submit an annual report to Congress that provides information concerning the premarket approval of devices labeled¹⁸ 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, the FDA Reauthorization Act of 2017 (FDARA)¹⁹ amended section 515A(a)(3) of the FD&C Act to require, among other things, FDA to provide, in its annual report to Congress, additional information related to the number of devices approved with a pediatric indication. Specifically, section 515A(a)(3) of the FD&C Act, as amended by FDARA, 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;*

¹⁶ Public Law 110-85.

¹⁷ 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 *pediatric subpopulations* by reference to section 520(m)(6)(E)(ii) of the FD&C Act, which means one of the following subpopulations: neonates, infants, children, and adolescents.

¹⁸ See FD&C Act 201(k) for the definition of *label*; see 21 CFR 1.3 for the definition of *labeling*.

¹⁹ 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.

Further, section 502(d) of FDARA states that,

- (1) *IN GENERAL. Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall convene a public meeting on the development, approval or clearance, and labeling of pediatric medical devices. The Secretary shall invite to such meeting representatives from the medical device industry, academia, recipients of funding under section 305 of the Pediatric Medical Device Safety and Improvement Act of 2007 (Public Law 110–85; 42 U.S.C. 282 note), medical provider organizations, and organizations representing patients and consumers.*
- (2) *TOPICS. The meeting described in paragraph (1) shall include consideration of ways to—*
 - (A) *improve research infrastructure and research networks to facilitate the conduct of clinical studies of devices for pediatric populations that would result in the approval or clearance, and labeling, of medical devices for such populations;*
 - (B) *appropriately use extrapolation under section 515A(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e–1(b));*
 - (C) *enhance the appropriate use of postmarket registries and data to increase pediatric medical device labeling;*

- (D) *increase Food and Drug Administration assistance to medical device manufacturers in developing devices for pediatric populations that are approved or cleared, and labeled, for their use; and*
- (E) *identify current barriers to pediatric device development and incentives to address such barriers.*

(3) REPORT. The report submitted under section 515A(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e–1(a)(3)) with respect to the calendar year in which the meeting described in paragraph (1) is held shall include a summary of, and responses to, recommendations raised in such meeting.

This is the ninth report of the FDA pursuant to section 515A(a)(3) of the FD&C Act since FDAAA’s enactment. This fiscal year (FY) 2018 report includes information and accounting with respect to the approval of devices that are indicated for use in pediatric patients or that are intended to treat, diagnose, or cure diseases from which pediatric patients suffer, as required under section 515A of the FD&C Act for approvals made during FY 2018.²⁰ Information submitted under section 515A(a) of the FD&C Act assisted in the development of this report. In addition, this report includes background information regarding section 515A of the FD&C Act and FDA’s implementation of that provision.

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:²¹

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

²⁰ 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.

²¹ 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.

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 at the time of diagnosis or treatment (i.e., inclusive of the year prior to their 22nd birthday). Additionally, pediatric subpopulations are specified 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) to mean one of the following subpopulations: neonates, infants, children, and adolescents. Generally, FDA views the approximate age ranges for these pediatric subpopulations as follows:²²

- 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* amending the regulations on premarket approval of devices in 21 CFR Part 814 to require persons who submit certain device applications to include, if readily available, a description of information relating to pediatric subpopulations that suffer from the disease or condition that a device is intended to treat, diagnose, or cure, and the number of affected pediatric patients.²³ 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 regulations.²⁴ On May 1, 2014, FDA issued a final guidance document entitled *Providing Information about Pediatric Uses of Medical Devices*.²⁵

²² 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>.

²³ *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*, Final Rule (79 FR 1735 at 1735-1741) (January 10, 2014).

²⁴ 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>.

²⁵ 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>.

Later, on June 21, 2016, FDA issued a final guidance document entitled *Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices*.²⁶ 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

In FY 2018, from FDA's Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER), there were 59 device approvals.²⁷ Of those 59 device approvals, 22 of them (or 37 percent), including 21 PMAs and one HDE, had an indication for use in a pediatric population or subpopulation. Among the 21 PMAs indicated for use in a pediatric population or subpopulation, there was a median of 180 FDA Days²⁸ and 359 total elapsed days until approval. Also, for the one HDE indicated for use in a pediatric population or subpopulation, the median time to review was 216 FDA Days and 277 total elapsed days until approval.

Per section 515A of the FD&C Act, FDA is providing the following FY 2018 figures in this report to Congress:

- Four PMAs included data from adults which supported FDA's determination of a reasonable assurance of safety and effectiveness in pediatric patients.²⁹

²⁶ 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>.

²⁷ In this report, FDA includes statistical data on the pediatric use of devices approved by CDRH and CBER.

²⁸ 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>.

²⁹ See section 515A(a)(3)(G) of the FD&C Act.

- For one device approval, FDA relied on data from one pediatric subpopulation to support a determination of a reasonable assurance of safety and effectiveness in another pediatric subpopulation.³⁰
- Based on a review of data available to FDA, such as the PMA and HDE periodic reports received in FY 2018, there were 18 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.³¹

From FY 2008 to FY 2018, 525 PMAs and HDEs have been approved by CDRH and CBER, combined, with an average of 47.73 device approvals per year.³² Of these device approvals, 134³³ were approved with an indication for use in a pediatric population or subpopulation at the initial time of the marketing authorization. Since FY 2008, there has generally been an increase in PMA and HDE approvals with non-pediatric indications of devices reviewed by CDRH and CBER (Figure 1A and Appendix B – Table 1). From FY 2008 to FY 2018, the greatest number (i.e., 73) of PMA or HDE approvals was in FY 2016, and the lowest number of PMA or HDE approvals (i.e., 21) was in FY 2010.³⁴

Figure 1A demonstrates the PMA and HDE approvals, from FY 2008 to FY 2018, with non-pediatric indications (red) and with pediatric (blue) indications of devices reviewed by CDRH and CBER.

Figure 1A. PMA and HDE approvals with non-pediatric indications (red) and with pediatric indications (blue) from FY 2008-FY 2018.

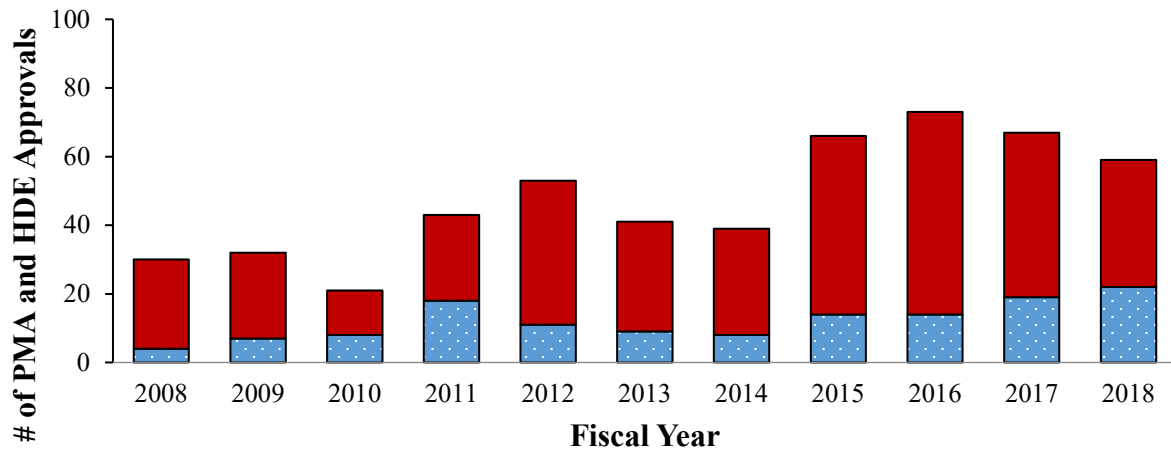
³⁰ See section 515A(a)(3)(H) of the FD&C Act.

³¹ See section 515A(a)(3)(B) of the FD&C Act. PMAs are subject to the periodic reporting requirements of the PMA approval order (21 CFR 814.82(a), 21 CFR 814.84(b)). Similarly, HDEs must submit periodic reports in accordance with the HDE approval order under 21 CFR 814.126(b).

³² See Appendix B – Table 1. Note that all the numbers for the prior years have been updated to include devices approved by CDRH and CBER.

³³ This number was obtained by totaling PMA and HDE approvals indicated for pediatric patients from FY 2008 to FY 2018; see Appendix B – Table 1.

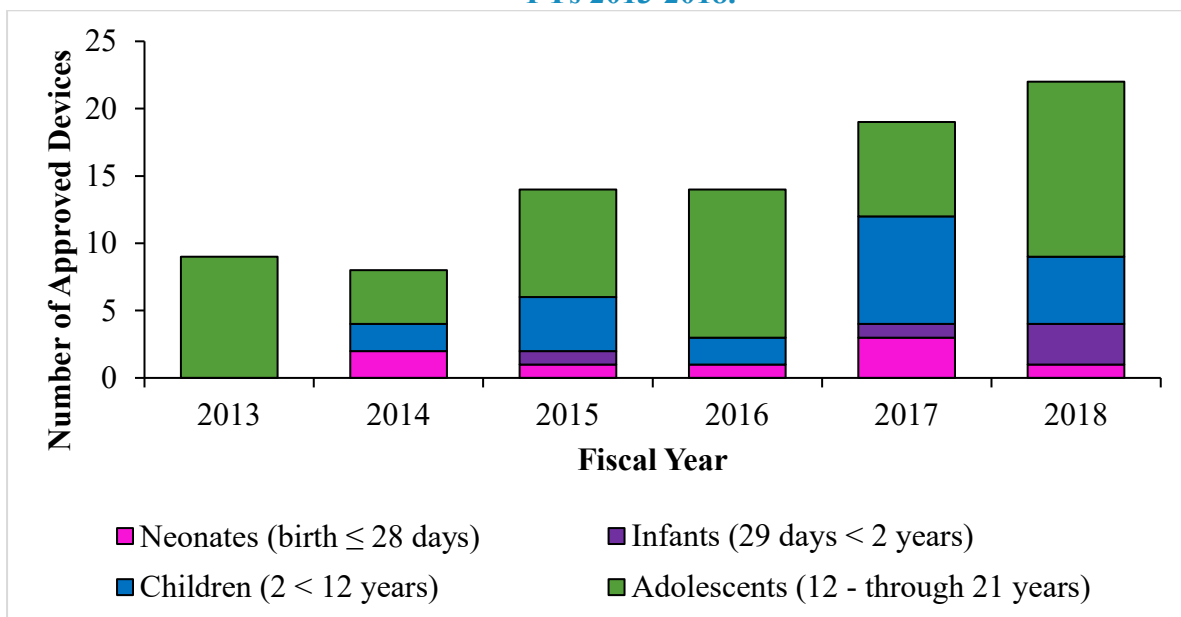
³⁴ These numbers represent the combined PMA or HDE approvals by CDRH and CBER in FY 2017 and in FY 2010.



■ PMA and HDE Approvals (Pediatric) ■ PMA and HDE Approvals (Non-Pediatric)

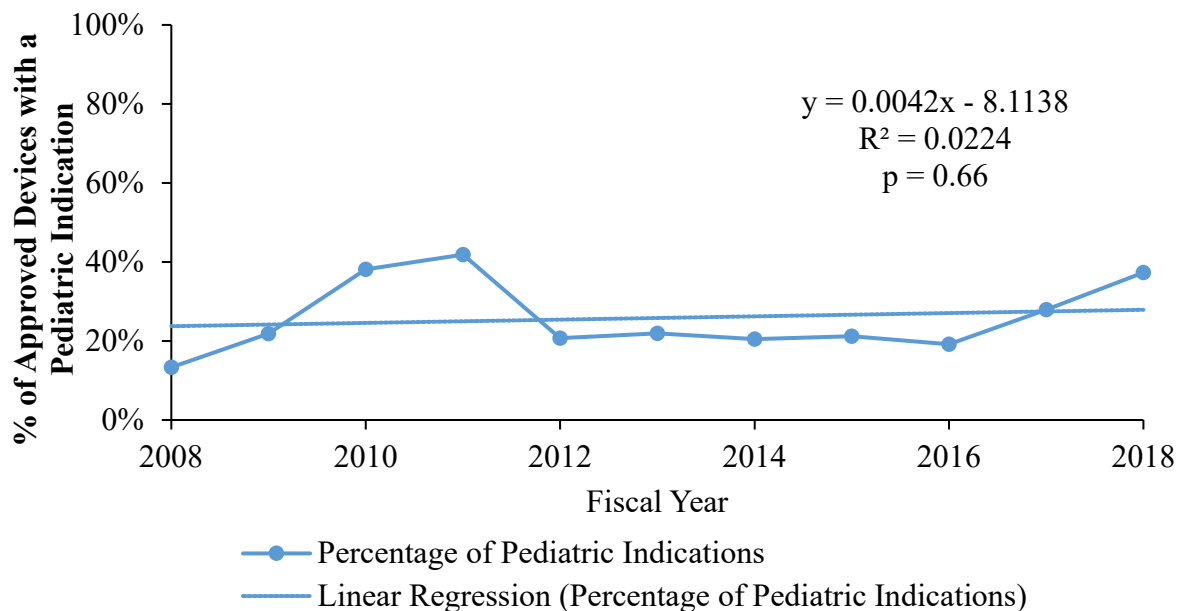
Figure 1B shows the PMA and HDE approvals indicated for pediatric subpopulations by age for devices reviewed by CDRH and CBER from FY 2013 to FY 2018. These PMA and HDE approvals are categorized by the youngest age for which there was an indication for use. In rare cases, a device may have only been used in a specific subpopulation. See also Appendix B – Table 2 for a more detailed breakdown of PMA and HDE approvals indicated for pediatric subpopulations by age for devices reviewed by CDRH and CBER from FY 2013 to FY 2018.

Figure 1B. PMA and HDE approvals by youngest suggested pediatric subpopulation from FYs 2013-2018.



Appendix A includes a detailed summary of each of the FY 2018 PMA and HDE approvals that were indicated for use in a pediatric population or pediatric subpopulation.

Figure 2. Percentage of PMA and HDE devices indicated for use within the pediatric population (Mean = 26% (134/525)).



Since FY 2008, the largest number of PMA and HDE approvals by CDRH and CBER (i.e., 22) for an indication that included a pediatric population or subpopulation was in FY 2018 (see Appendix B – Table 1). The largest percentage of PMA and HDE approvals (i.e., 42 percent) for an indication that included a pediatric population or subpopulation was in FY 2011 (see Figure 2 and Appendix B – Table 1). On average for the last 11 fiscal years, only 26 percent of the total PMA and HDE approvals in each fiscal year have had 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 with pediatric indications declined to 21 percent, only rising again to 28 percent in FY 2017 and 37 percent in FY 2018.

IV. Report on the 2018 Public Meeting on Pediatric Medical Device Development

As mandated by section 502(d) of the FDARA, FDA held a public meeting on August 13-14, 2018, on the development, approval or clearance, and labeling of pediatric medical devices.³⁵ This meeting brought together representatives from the medical device industry, academia, recipients of funding under section 305 of the Pediatric Medical Device Safety and Improvement Act of 2007, medical provider organizations, and organizations representing patients and consumers.

The purpose of the public meeting was to identify strategies to enhance the medical device ecosystem to cultivate development and innovation of devices that serve the unique needs of pediatric populations.

Comments were also gathered and reviewed from participants and stakeholders after the meeting through the solicitation of public comments in a *Federal Register* public docket.³⁶

The following provides a summary of, and responses to, the meeting's proposed strategies and the feedback received from stakeholders related to this meeting, as well as a summary of potential next steps.

A. Summary of the Proposed Strategies and the Associated Stakeholder Feedback

Each subsection below presents a strategy proposed by FDA at the meeting to help enhance the medical device ecosystem in addition to information on any feedback received from stakeholders on that strategy, either during or after the meeting.

- 1. Improve research infrastructure and research networks to facilitate the conduct of clinical studies of devices for pediatric populations that would result in the approval or clearance, and labeling, of medical devices for such populations*

To discuss this strategy, presentations on areas such as the following were given: the use of real-world evidence (RWE), CDRH's Pediatric Extrapolation for Devices (PEDs) Team, innovative clinical trial designs, and modeling and simulation.

³⁵ See Pediatric Medical Device Development Public Meeting - August 13-14, 2018, available at <https://wayback.archive-it.org/7993/20180908082950/https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm596777.htm>.

³⁶ 83 FR 7052 (February 16, 2018).

The feedback given by the stakeholders was based on their experiences using non-traditional data collection techniques, postmarket registries, and pediatric clinical trial infrastructure. Overarching themes and recommendations received from the public meeting or in the public docket included the following:³⁷

- a. Collecting data on unmet pediatric medical device needs;
- b. Establishing global clinical trial networks to conduct pediatric clinical investigations;
- c. Increasing the utilization of modeling, additive manufacturing, and simulation for extrapolating and evaluating medical devices;
- d. Increasing the support for the use of novel trial designs such as adaptive clinical trials or small pragmatic trials; and
- e. Increasing funding for the FDA Pediatric Device Consortia (PDC) Grants Program.³⁸

Evidence generation can be a costly and time-consuming experience for companies seeking to enter the U.S. marketplace. CDRH recognizes that novel clinical study designs may be an important way to potentially reduce the cost of generating sufficient evidence for regulatory purposes and has published two final guidance documents, entitled *Adaptive Designs for Medical Device Clinical Studies*³⁹ and *Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices*,⁴⁰ each containing recommendations for consideration.

2. *Appropriately use extrapolation under section 515A(b) of the FD&C Act*

The final guidance document entitled *Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices*⁴¹ explains the circumstances in which it may be appropriate to extrapolate existing medical device data to support pediatric device indications in marketing

³⁷ For more information about the public meeting and transcripts, see <https://wayback.archive-it.org/7993/20180908082950/https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm596777.htm>.

³⁸ FDA funds the PDC that provides expert advising and support services to innovators of children's devices. These services include business and regulatory consulting, as well as device-testing capabilities. For more information, see the PDC Grants Program web page, available at <https://www.fda.gov/industry/developing-products-rare-diseases-conditions/pediatric-device-consortia-grants-program>.

³⁹ This final guidance document, published in July 2016, is available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/adaptive-designs-medical-device-clinical-studies>.

⁴⁰ This final guidance document, published in August 2017, is available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-real-world-evidence-support-regulatory-decision-making-medical-devices>.

⁴¹ 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>.

applications. *Extrapolation*, as described in the guidance document, refers to the leveraging process whereby an indication for use of a device in a new pediatric patient population can be supported by existing clinical data from a studied patient population. For pediatric medical devices, extrapolated data may come from adults or a different pediatric subpopulation.

During the public meeting, FDA shared details about how extrapolation has been used in the review of pediatric medical devices, including the development of the PEDs Team, which is a first-of-its-kind consultation team. The PEDs Team brings together technical pediatric review staff from across FDA on a voluntary basis to evaluate medical device applications for pediatric use that may benefit from novel extrapolation techniques. Meeting discussions and comments submitted to the docket emphasized the importance of extrapolation for pediatric indications. The feedback received also focused on the need for further clarification by FDA on the types of data that can be extrapolated and the need for a further explanation by FDA on the use of extrapolated data.

3. *Enhance the appropriate use of postmarket registries and data to increase pediatric medical device labeling*

Clinical data from registries and other collaborative data sources may permit the generation of clinical evidence to support marketing applications directed to enhance pediatric patient access to safe and effective medical devices. Through collaborations with medical device stakeholders, such as the National Evaluation System of health Technology Coordinating Center (NESTcc) and PDC, FDA has been exploring ways to develop mechanisms that can help advance innovation in pediatric medical devices, including utilization of RWE. The meeting included discussions related to FDA's activities and challenges faced in these areas, and the presenters shared their feedback on use of such data.

Recommendations to enhance appropriate use of postmarket registries and data discussed during the meeting and in comments submitted to the public docket included:

- a. Streamlining the integrations of real-world data through universal device registries;
- b. Increasing the utilization of hybrid models with real-world data and small confirmatory trials to decrease the time needed to approve/clear pediatric devices; and
- c. Developing national registries to facilitate the inclusion of registry data in regulatory submissions.

4. *Increase FDA's assistance to medical device manufacturers in developing devices for pediatric populations that are approved or cleared and labeled for this population's use*

FDA is committed to continuing to support the development and availability of medical devices labeled for pediatric populations.⁴² During the meeting, presentations on FDA's efforts to streamline pediatric medical device reviews were followed by a public discussion on how the Agency can further support the medical device ecosystem. The discussion focused on the differences between the review of pediatric and adult medical devices and the need for the least burdensome regulatory practices.⁴³ To overcome regulatory barriers, some proposals that were discussed at the meeting and in comments submitted to the docket included the following:

- a. Developing a pediatric-specific review team;
 - b. Expanding the FDA's Medical Device User Fee Amendments (MDUFA) funding to help ensure pediatric experts are performing reviews for pediatric devices;⁴⁴
 - c. Developing a pediatric-specific review pathway and/or making modifications to the regulatory process to provide a streamlined review for pediatric medical devices;
 - d. Requiring FDA to ask all sponsors with a device application to explore extrapolation to the pediatric population; and
 - e. Encouraging the Agency to work with other Department of Health and Human Services' agencies and establish public-private partnerships to increase the development of and access to pediatric medical devices.
5. *Identify current barriers to pediatric device development and incentives to address such barriers*

FDA received several comments to address current barriers and incentives for pediatric device development that have not already been addressed in this report. These comments are presented below, organized by topic. It should be noted that some of the comment's proposals are outside of FDA's current statutory authority.

First, the differences in the pediatric drug market and the pediatric device market were discussed. Incentives used in the pediatric drug market (i.e., those provided through the Pediatric Research

⁴² For more information, see FDA's Pediatric Medical Devices web page, available at <https://www.fda.gov/medical-devices/products-and-medical-procedures/pediatric-medical-devices>.

⁴³ For more information, see FDA's final guidance document entitled *The Least Burdensome Provisions: Concept and Principles* (February 2019), available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/least-burdensome-provisions-concept-and-principles>.

⁴⁴ See MDUFA IV Performance Goals and Procedures, Fiscal Years 2018 through 2022, available at <https://www.fda.gov/media/102699/download>.

Equity Act⁴⁵ and the Best Pharmaceuticals for Children Act (BPCA)⁴⁶ were discussed as a potential model for the device market. However, it was mentioned during the meeting and by the comments received to the docket that the drug and device ecosystems were substantially different and that specific laws and regulations to spur development and labeling are different for drugs and devices. It was also mentioned that some of the BPCA incentives, such as patent extensions, are generally ineffective or not an option in the device environment.

Second, the lack of a financial infrastructure for investment into pediatric medical devices was discussed. Participants stated that the current marketplace does not provide sufficient financial returns for pediatric medical device development compared to the broader medical device market and emphasized that early-stage investors are reluctant to invest in pediatric medical devices due to high research and development costs. To overcome these barriers, suggestions from the public included establishing financial incentives to assist in the development of pediatric devices by reducing costs across the total product life cycle. Proposed financial incentives submitted to the public docket included a guaranteed reimbursement plan by payors during a clinical study, increased funding to the PDC to support the research and development of pediatric medical devices, a tax credit for pediatric HDEs similar to the tax credit that currently exists for orphan drugs, increasing funding for FDA's strategic initiatives, and other pediatric device research and development tax incentives.

Stakeholders maintained that the diseases and conditions for which pediatric devices are needed often do not represent a commercially viable market opportunity for traditional medical device companies. For example, when recruiting patients for a clinical study, small numbers of geographically dispersed pediatric patients with a given disease or condition make it difficult to accrue patients over a reasonable time frame. Further, there are special considerations for developing devices for a pediatric population, such as growth of the child, in comparison to developing devices for adults. To assist in reducing the burden from the small population and pediatric considerations, the public recommended that an infrastructure be developed by the pediatric ecosystem to support pediatric device clinical trials. Currently, little infrastructure exists beyond individual pediatric-focused hospitals and the PDC network. A supportive infrastructure could potentially offer a network for efficiently conducting studies. In addition, to support the initial research and development of pediatric medical devices, meeting participants recommend bolstering the National Institute of Health's role in fostering research to facilitate the development of medical devices intended for children.

Third, reimbursement options and opportunities across the total product life cycle for devices with a pediatric indication, compared to those for devices with an adult indication, may be

⁴⁵ Pediatric Research Equity Act of 2003 (Public Law 108-155).

⁴⁶ Best Pharmaceuticals for Children Act (Public Law 107-109).

distinct. For example, to overcome reimbursement barriers for pediatric devices, some stakeholders recommended increasing and standardizing the reimbursement support from public insurance coverage for pediatric medical devices during both evidence generation periods and after regulatory marketing approval. However, this proposal is outside of FDA’s jurisdiction.

B. Next Steps

The 2018 pediatric medical device development public meeting brought together many stakeholders from the pediatric medical device community to identify strategies to enhance the medical device ecosystem to cultivate the development and innovation of devices that serve the unique needs of pediatric populations.

FDA has been actively identifying opportunities to support the development and innovation of medical devices designed and labeled for children. Based on stakeholder feedback, FDA is considering various approaches to encourage device innovation for medical conditions that impact pediatric populations. For example, FDA is considering proposals to advance research infrastructures and extrapolation tools to streamline data requirements, to grow the use of RWE and postmarket registries to expand pediatric medical device labeling, and to broaden FDA’s assistance to the pediatric ecosystem to increase the number of pediatric devices.

The public meeting verified a long-standing public health concern — that is, children and special populations require equitable benefit from medical technology innovation. FDA remains committed to supporting the development and availability of medical devices designed, evaluated, and approved for the unique needs of pediatric populations. Via efforts led by FDA’s nascent Program in Pediatrics and Special Populations housed in CDRH, the Agency, with input from stakeholders, is developing internal infrastructures, which are intended to help address the needs of innovators and to integrate with FDA’s collaborative multi-stakeholder initiatives, to foster a robust innovation ecosystem for pediatric medical device development. For more information on FDA’s efforts related to pediatric medical devices, refer to FDA’s Pediatric Medical Devices web page.⁴⁷

V. Conclusion

Since FY 2008, FDA has submitted reports to Congress providing information concerning annual premarket approvals of devices indicated for pediatric use. This is FDA’s ninth report submitted to Congress pursuant to section 515A(a)(3) of the FD&C Act.

⁴⁷ <https://www.fda.gov/medical-devices/products-and-medical-procedures/pediatric-medical-devices>.

This report includes information on medical device approvals in FY 2018, which includes devices approved by CDRH or CBER, that were indicated for use in pediatric populations or subpopulations. Based on the information summarized in this report, there have been limited changes in PMA or HDE approvals indicated for use in pediatric populations or subpopulations since FY 2008. Since the passage of FDAAA, the number of devices approved for pediatric populations has generally increased; however, the percentage of devices indicated for use in the pediatric population out of the total devices approved each year has remained relatively constant (see Appendix B – Table 1).

FDA is committed to continue to work with the pediatric community to support the advancement, development, and availability of medical devices for use in pediatric populations. FDA takes seriously its responsibility to assure that medical 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 medical devices, refer to FDA’s Pediatric Medical Devices web page.⁴⁸

⁴⁸ <https://www.fda.gov/medical-devices/products-and-medical-procedures/pediatric-medical-devices>.

VI. Appendix A

FY 2018's Device PMA and HDE Approvals Indicated for Use in Pediatric Patients (Including Review Times)

All devices included in Appendix A are approved and labeled for use in a pediatric population.⁴⁹ In this appendix, CDRH and CBER provide the youngest suggested pediatric subpopulations, as designated under section 515A(c) of the FD&C Act, based on analyses of publicly available information, such as the device's Summary of Safety and Effectiveness Data (SSED), Summary of Safety and Probable Benefit (SSPB), and labeling, as well as additional factors, including but not limited to average pediatric anthropometric measurements and device dimensions.

Device Information

BLAZER OPEN-IRRIGATED ABLATION CATHETER AND INTELLANAV OPEN-IRRIGATED ABLATION CATHETER

The Blazer and IntellaNav Open-Irrigated Ablation Catheters, when used with a compatible Radiofrequency Controller and Irrigation Pump, are indicated for:

- cardiac electrophysiological mapping;
- delivering diagnostic pacing stimuli;
- RF ablation of sustained or recurrent type I atrial flutter in patients age 18 years or older; and
- Treatment of drug refractory, recurrent, symptomatic, paroxysmal atrial fibrillation (PAF) in patients age 18 years or older, when used with a compatible mapping system.

Manufacturer	Boston Scientific
Number	P150005/S014
Filing Date	5/16/2017
Approval Date	12/21/2017
Youngest Suggested Pediatric Subpopulation:	18 and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	177
Total Elapsed Days	219

VITROS IMMUNODIAGNOSTIC PRODUCTS HIV COMBO REAGENT PACK VITROS IMMUNODIAGNOSTIC PRODUCTS HIV COMBO CALIBRATOR

VITROS Immunodiagnostic Products HIV Combo Reagent Pack is for the simultaneous qualitative detection of antibodies to Human Immunodeficiency Virus types 1, including group M and O, and/or 2 (anti-HIV-1 and anti-HIV-2) and HIV p24 antigen in human serum and plasma (heparin and EDTA) in adults, pregnant women, adolescents and children (as young as 2 years of age), using the VITROS ECi/ECiQ Immunodiagnostic Systems.

⁴⁹Additional information pertaining to these devices can be found in the SSED or the SSPB by searching the PMA or HDE number, respectively. The PMA and HDE approvals are listed in chronological order from earliest approval date. FDA's Medical Device Databases web page is available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases>.

A reactive result with the VITROS HIV Combo test does not distinguish between the detection of HIV-1 p24 antigen, antibodies to HIV-1, and antibodies to HIV-2.

The results of the VITROS HIV Combo Test, in conjunction with other serological evidence and clinical information, may be used as an aid in the diagnosis of infection with HIV-1 and/or HIV-2. The VITROS HIV Combo Test is not intended for use in screening blood or plasma donors. The effectiveness of the VITROS HIV Combo assay for use in screening blood or plasma donors has not been established. However, this assay can be used as a blood donor screening assay in urgent situations where traditional licensed blood donor screening tests are unavailable or their use is impractical.

It is not intended for newborn screening or for use with cord blood specimens or specimens from individuals less than 2 years of age.

The VITROS HIV Combo Calibrator is for use in the calibration of the VITROS 3600 Immunodiagnostic System.

Manufacturer	Ortho-Clinical Diagnostics, Inc
Number	BP160122
Filing Date	12/19/2016
Approval Date	12/13/2017
Youngest Suggested Pediatric Subpopulation:	Adolescents and children (as young as 2 years of age)
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	180
Total Elapsed Days	359

LIFEPAK CR® PLUS DEFIBRILLATOR, LIFEPAK EXPRESS® DEFIBRILLATOR, AND CHARGE-PAK® BATTERY CHARGER

The LIFEPAK CR Plus and LIFEPAK EXPRESS defibrillators are indicated for use on patients in cardiac 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 devices are intended for use by personnel who have been trained in their operation. Users should have received training in basic life support/AED, advanced life support or a physician-authorized emergency medical response training program.

The defibrillators may be used with QUIK-PAK defibrillation pads only on adults and children who are 8 years old or more, or who weigh more than 25kg (55lbs). The defibrillators may be used on children who are less than 8 years old or weigh less than 25k (55lbs) with Infant/Child Reduced Energy Defibrillation Electrodes.

The defibrillators may be used with the CHARGE-PAK battery charger.

Manufacturer	Physio-Control, Inc.
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Number	P160012
Filing Date	4/27/2016
Approval Date	12/21/2017
Youngest Suggested Pediatric Subpopulation:	Infants and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	180
Total Elapsed Days	603
X Series®, R Series®, AED Pro®, AED 3™ BLS Professional Defibrillators, Pro-Padz Radiotransparent Electrode, SurePower™ Battery Pack, SurePower II™ Battery Pack, AED Pro® Non-Rechargeable Lithium Battery Pack, AED 3™ Battery Pack, SurePower™ Charger, and SurePower™ Single Bay Charger	
<p>The ZOLL® X Series®, R Series®, AED Pro®, and AED 3 BLS® devices use two multifunction defibrillation electrodes to acquire a patient's electrocardiogram (ECG). If this device detects an abnormal heartbeat, it may advise the user that a high-energy shock is necessary. The user interface will provide voice instructions to guide the user through the rescue process including cardiopulmonary resuscitation (CPR). The device will provide an audible rhythmic beeping sound to help the user deliver the correct rate of compressions while giving CPR. If a defibrillation shock is required the device will prompt the user to deliver an electrical shock through the electrodes.</p>	
Manufacturer	ZOLL Medical Corporation
Number	P160022
Filing Date	7/7/2016
Approval Date	12/27/2017
Youngest Suggested Pediatric Subpopulation:	Neonates and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	180
Total Elapsed Days	538
Lifeline/ReviveR DDU-100, Lifeline/ReviveR AUTO DDU-120, Lifeline/ReviveR VIEW DDU-2300, Lifeline/ReviveR VIEW AUTO DDU-2200, Lifeline/ReviveR ECG DDU-2450, and Lifeline/ReviveR ECG+ DDU-2475 Automated External Defibrillators	
<p>The Lifeline/ReviveR DDU-100 series Automated External Defibrillator (AED) is indicated for use on victims of sudden cardiac arrest (SCA) who are:</p> <ul style="list-style-type: none"> • Unconscious and unresponsive; and • Not breathing or not breathing normally. <p>Lifeline/ReviveR DDU-100 series AEDs may be used with Defibtech adult defibrillation pads (model number DDP-100). For patients under 8 years old or weighing less than 55 lbs (25 kg), use Defibtech child/infant defibrillation pads (model number DDP-200P), if available.</p> <p>The Lifeline/ReviveR DDU-2000 series Automated External Defibrillator (AED) is indicated for use on victims of sudden cardiac arrest (SCA) who are:</p> <ul style="list-style-type: none"> • Unconscious and unresponsive; and • Not breathing or not breathing normally. 	

Lifeline/ReviveR DDU-2000 series AEDs may be used with Defibtech adult defibrillation pads (model number DDP-2001). For patients under 8 years old, or weighing less than 55 lbs (25 kg), use Defibtech child/infant defibrillation pads (model number DDP-2002), if available

Manufacturer	Defibtech LLC
Number	P160032
Filing Date	8/3/2016
Approval Date	2/1/2018
Youngest Suggested Pediatric Subpopulation:	Infants and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	180
Total Elapsed Days	547

BD ONCLARITY HPV ASSAY

The BD Onclarity HPV Assay is a qualitative in vitro test for the detection of Human Papillomavirus in cervical specimens collected by a clinician using an endocervical brush/spatula combination or broom and placed in a BD SurePath vial. The test utilizes amplification of target DNA by Polymerase Chain Reaction (PCR) and nucleic acid hybridization for the detection of 14 high-risk (HR) HPV types in a single analysis. The test specifically identifies types 16, 18 and 45 while concurrently detecting the other HR HPV types that include 31, 33, 35, 39, 51, 52, 56, 58, 59, 66 and 68.

Manufacturer	Becton, Dickinson and Company
Number	P160037
Filing Date	8/24/2016
Approval Date	2/12/2018
Youngest Suggested Pediatric Subpopulation:	Women 21 years and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	180
Total Elapsed Days	537

MINIMED 630G SYSTEM WITH SMARTGUARD

The MiniMed 630G System with SmartGuard is intended for continuous delivery of basal insulin (at user selected rates) and administration of insulin boluses (in user selectable amounts) for the management of diabetes mellitus in persons fourteen 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 630G system includes SmartGuard, which can be programmed to temporarily suspend delivery of insulin for up to two hours when the sensor glucose value falls below a predefined threshold value.

The MiniMed 630G System with SmartGuard consists of the following devices: MiniMed 630G Insulin Pump, Guardian Sensor (3), One-press serter, Guardian Link (3) transmitter system, CareLink USB, CONTOUR NEXT LINK 2.4 Wireless Meter, and CONTOUR NEXT Test Strips. The system requires a prescription.

The MiniMed 630G System with SmartGuard is not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a finger stick may be required. All therapy

adjustments should be based on measurements obtained using a home glucose monitor and not on values provided by the MiniMed 630G system.

The MiniMed 630G System with SmartGuard is not intended to be used directly for preventing or treating hypoglycemia but to suspend insulin delivery when the user is unable to respond to the SmartGuard Suspend on Low alarm to take measures to prevent or treat hypoglycemia themselves. Therapy to prevent or treat hypoglycemia should be administered according to the recommendations of the user's healthcare provider.

Manufacturer	Medtronic MiniMed, Inc.
Number	P150001/S021
Filing Date	8/17/2017
Approval Date	2/13/2018
Youngest Suggested Pediatric Subpopulation:	14 and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	180
Total Elapsed Days	180

MINIMED 670G SYSTEM

The Medtronic MiniMed 670G 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, fourteen 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 670G System includes SmartGuard technology, which can be programmed to automatically adjust delivery of basal insulin based on Continuous Glucose Monitor 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.

The Medtronic MiniMed 670G System consists of the following devices: MiniMed 670G insulin pump, the Guardian Link (3) Transmitter, the Guardian Sensor (3), One-Press Serter, and the Contour NEXT Link 2.4 Glucose Meter. The system requires a prescription.

The Guardian Sensor (3) glucose values are not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a finger stick may be required. All therapy adjustments should be based on measurements obtained using a home glucose monitor and not on values provided by the Guardian Sensor (3).

Manufacturer	Medtronic MiniMed
Number	P160017/S017
Filing Date	8/17/2017
Approval Date	2/13/2018
Youngest Suggested Pediatric Subpopulation:	14 years and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	180
Total Elapsed Days	180

GUARDIAN CONNECT SYSTEM

The Guardian Connect system is indicated for continuous or periodic monitoring of glucose levels in the interstitial fluid under the skin, in patients (14 to 75 years of age) with diabetes mellitus.

The Guardian Connect system provides real-time glucose values and trends through a Guardian Connect app installed on a compatible consumer electronic mobile device. It allows users to detect trends and track patterns in glucose concentrations. The Guardian Connect app alerts if a Guardian Sensor (3) glucose level reaches, falls below, rises above, or is predicted to surpass set values.

The Guardian Sensor (3) glucose values are not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a finger stick may be required. All therapy adjustments should be based on measurements obtained using a home glucose monitor and not on values provided by the Guardian Sensor (3).

The Guardian Connect system is comprised of the following devices: Guardian Connect app, Guardian Sensor (3), and the Guardian Connect transmitter.

Manufacturer	Medtronic MiniMed, Inc.
Number	P160007
Filing Date	3/9/2016
Approval Date	3/8/2018
Youngest Suggested Pediatric Subpopulation:	14 to 75 years of age
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	256
Total Elapsed Days	729

LIPOSORBER LA-15 SYSTEM

The LIPOSORBER® LA-15 System is indicated for use in the treatment of adult and pediatric patients with nephrotic syndrome associated with primary focal segmental glomerulosclerosis, when:

- Standard treatment options, including corticosteroid and/or calcineurin inhibitors treatments, are unsuccessful or not well tolerated and the patient has a GFR \geq 60 ml/min/1.73m² or
- The patient is post renal transplantation.

Manufacturer	Kaneka Pharma America
Number	H170002
Filing Date	6/16/2017
Approval Date	3/20/2018
Youngest Suggested Pediatric Subpopulation:	Children and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	216
Total Elapsed Days	277

GORE CARDIOFORM SEPTAL OCCLUDER

The GORE® CARDIOFORM Septal Occluder is a permanently implanted device indicated for the percutaneous, transcatheter closure of the following defects of the atrial septum:

- Ostium secundum atrial septal defects (ASDs).

- Patent foramen ovale (PFO) to reduce the risk of recurrent ischemic stroke in patients, predominantly between the ages of 18 and 60 years, who have had a cryptogenic stroke due to a presumed paradoxical embolism, as determined by a neurologist and cardiologist following an evaluation to exclude known causes of ischemic stroke.

Manufacturer	W.L. Gore & Associates, Inc.
Number	P050006/S060
Filing Date	7/31/2017
Approval Date	3/30/2018
Youngest Suggested Pediatric Subpopulation:	18 to 60 years
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	179
Total Elapsed Days	242

MEDTRONIC DBS THERAPY FOR EPILEPSY

Bilateral stimulation of the anterior nucleus of the thalamus (ANT) using the Medtronic DBS System for Epilepsy is indicated as an adjunctive therapy for reducing the frequency of seizures in individuals 18 years of age or older diagnosed with epilepsy characterized by partial-onset seizures, with or without secondary generalization, that are refractory to three or more antiepileptic medications.

The Medtronic DBS System for Epilepsy has demonstrated safety and effectiveness for patients who average six or more seizures per month over the three most recent months prior to implant of the DBS system (with no more than 30 days between seizures). The Medtronic DBS System for Epilepsy has not been evaluated in patients with less frequent seizures.

Manufacturer	Medtronic, Inc.
Number	P960009/S219
Filing Date	2/24/2015
Approval Date	4/27/2018
Youngest Suggested Pediatric Subpopulation:	18 years and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	193
Total Elapsed Days	1158

CUSTOMFLEX ARTIFICIAL IRIS

The CustomFlex™ Artificial Iris is indicated for use in children and adults for the treatment of full or partial aniridia resulting from congenital aniridia, acquired defects, or other conditions associated with full or partial aniridia.

Manufacturer	Clinical Research Consultants, Inc.
Number	P170039
Filing Date	12/01/2017
Approval Date	5/30/2018
Youngest Suggested Pediatric Subpopulation:	Children and Adults
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	180

Total Elapsed Days	180
LOW-PROFILE VISUALIZED INTRALUMINAL SUPPORT (LVIS) AND LVIS JR.	
<p>The LVIS and LVIS Jr. are indicated for use with neurovascular embolization coils in patients ≥ 18 years of age for the treatment of wide-neck (neck width ≥ 4 mm or dome to neck ratio < 2) saccular intracranial aneurysms arising from a parent vessel with a diameter ≥ 2.0 mm and ≤ 4.5 mm.</p>	
Manufacturer	MicroVention, Inc.
Number	P170013
Filing Date	4/6/2017
Approval Date	5/30/2018
Youngest Suggested Pediatric Subpopulation:	18 years and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	320
Total Elapsed Days	419
T:SLIM X2 INSULIN PUMP WITH BASAL-IQ TECHNOLOGY	
<p>The t:slim X2 Insulin Pump with Basal-IQ Technology (the System) consists of the t:slim X2 Insulin Pump which contains the Basal-IQ technology, and a continuous glucose monitor (CGM). Compatible CGMs include the Dexcom G5 Mobile CGM and integrated continuous glucose monitors (iCGMs) that are listed in the labeling for this device.</p>	
<p>The t:slim X2 Insulin Pump is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The t:slim X2 Insulin Pump can be used solely for continuous insulin delivery and as part of the t:slim X2 Insulin Pump with Basal-IQ Technology System.</p>	
<p>When the System is used with the Dexcom G5 Mobile CGM or a compatible iCGM, the Basal-IQ Technology can be used to suspend insulin delivery based on CGM sensor readings.</p>	
<p>The Dexcom G5 Mobile CGM Continuous Glucose Monitoring System (Dexcom G5) is indicated for the management of diabetes in persons age 2 years and older. The Dexcom G5 is designed to replace fingerstick blood glucose testing for diabetes treatment decisions. Interpretation of the System results should be based on the trends and patterns seen with several sequential readings over time. The Dexcom G5 also aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. The Dexcom G5 is intended for single patient use and requires a prescription.</p>	
Manufacturer	Tandem Diabetes Care, Inc.
Number	P180008
Filing Date	2/26/2018
Approval Date	6/21/2018
Youngest Suggested Pediatric Subpopulation:	2 years and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	115
Total Elapsed Days	115

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 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 indicated for use as an adjunctive device to complement, not replace, information obtained from standard home blood glucose monitoring devices.

Manufacturer	Senseonics, Inc.
Number	P160048
Filing Date	10/26/2016
Approval Date	6/21/2018
Youngest Suggested Pediatric Subpopulation:	18 and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	281
Total Elapsed Days	603

MINIMED 670G SYSTEM

The Medtronic MiniMed 670G 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, seven 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 670G System includes SmartGuard technology, which can be programmed to automatically adjust delivery of basal insulin based on Continuous Glucose Monitor 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.

The Medtronic MiniMed 670G System consists of the following devices:

MiniMed 670G insulin pump, the Guardian Link (3) Transmitter, the Guardian Sensor (3), One-Press Serter, and the Contour NEXT Link 2.4 Glucose Meter. The system requires a prescription.

The Guardian Sensor (3) glucose values are not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a finger stick may be required. All therapy adjustments should be based on measurements obtained using a home glucose monitor and not on values provided by the Guardian Sensor (3).

Manufacturer	Medtronic MiniMed, Inc.
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Number	P160017/S031
Filing Date	1/26/2018
Approval Date	6/21/2018
Youngest Suggested Pediatric Subpopulation:	7 years and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	146
Total Elapsed Days	146
LIFEPAK® 1000 Defibrillator	
LIFEPAK® 1000 Defibrillator Lithium-Ion Rechargeable Battery	
LIFEPAK® 1000 Defibrillator Non-Rechargeable Battery	
LIFEPAK® 20 Defibrillator/Monitor (Refurbished)	
LIFEPAK® 20e Defibrillator/Monitor	
LIFEPAK® 15 Monitor/Defibrillator	
LIFEPAK® Lithium-ion Rechargeable Battery (for use with the LIFEPAK 15 Monitor/Defibrillator)	
<i>LIFEPAK 1000 Defibrillator:</i>	
The defibrillator is to be used in AED mode only on patients who are in cardiopulmonary arrest. The patient must be unresponsive, not breathing normally, and showing no signs of circulation.	
The defibrillator may be used with standard defibrillation pads (QUIK-COMBO ® Electrodes with REDI-PAK) only on adults and children who are 8 years old or more or who weigh more than 25 kg (55 lbs). The defibrillator may be used on children who are less than 8 years old or weigh less than 25 kg (55 lbs.) with Infant/Child Reduced Energy Defibrillation Electrodes.	
<i>LIFEPAK 20e and LIFEPAK 20 Defibrillator/Monitors:</i>	
The AED mode is to be used only on patients in cardiopulmonary arrest. The patient must be unconscious, pulseless, and not breathing normally before using the defibrillator to analyze the patient's ECG rhythm.	
In AED mode, the LIFEPAK 20 and LIFEPAK 20e defibrillator/monitor is not intended for use on pediatric patients less than 8 years old.	
<i>LIFEPAK 15 Defibrillator/Monitors:</i>	
AED mode is to be used only on patients in cardiopulmonary arrest. The patient must be unconscious, pulseless, and not breathing normally before using the defibrillator to analyze the patient's ECG rhythm. In AED mode, the LIFEPAK 15 monitor/defibrillator is not intended for use on pediatric patients less than 8 years old.	
Manufacturer	Physio-Control, Inc.
Number	P160026
Filing Date	7/25/2016
Approval Date	7/2/2018
Youngest Suggested Pediatric Subpopulation:	Infants and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	180

Total Elapsed Days	707
SURPASS STREAMLINE FLOW DIVERTER	
<p>The Surpass Streamline Flow Diverter is indicated for use in the endovascular treatment of patients (18 years of age and older) with unruptured large or giant saccular wide-neck (neck width ≥ 4 mm or dome-to-neck ratio < 2) or fusiform intracranial aneurysms in the internal carotid artery from the petrous segment to the terminus arising from a parent vessel with a diameter ≥ 2.5 mm and ≤ 5.3 mm.</p>	
Manufacturer	Stryker Neurovascular
Number	P170024
Filing Date	7/31/2017
Approval Date	7/13/2018
Youngest Suggested Pediatric Subpopulation:	18 years and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	180
Total Elapsed Days	347
FREESTYLE LIBRE 14 DAY FLASH GLUCOSE MONITORING SYSTEM	
<p>The FreeStyle Libre 14 Day Flash Glucose Monitoring System is a continuous glucose monitoring (CGM) device indicated for the management of diabetes in persons age 18 and older. It is designed to replace blood glucose testing for diabetes treatment decisions.</p>	
<p>The System detects trends and tracks patterns aiding in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Interpretation of the System readings should be based on the glucose trends and several sequential readings over time. The System is intended for single patient use and requires a prescription.</p>	
Manufacturer	Abbott Diabetes Care Inc.
Number	P160030/S017
Filing Date	4/24/2018
Approval Date	7/23/2018
Youngest Suggested Pediatric Subpopulation:	18 years and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	90
Total Elapsed Days	90
VISIAN® TORIC ICL (IMPLANTABLE COLLAMER LENS)	
<p>The Visian® Toric ICL is indicated for use in patients 21-45 years of age:</p> <ol style="list-style-type: none"> 1. for the correction of myopic astigmatism with spherical equivalent ranging from -3.0D to $\leq -15.0D$ (in the spectacle plane) with cylinder (spectacle plane) of 1.0D to 4.0D. 2. for the reduction of myopic astigmatism with spherical equivalent ranging from greater than -15.0D to -20.0D (in the spectacle plane) with cylinder (spectacle plane) 1.0D to 4.0D. 3. with an anterior chamber depth (ACD) of 3.00 mm or greater, when measured from the corneal endothelium to the anterior surface of the crystalline lens and a stable refractive history (within 0.5D for both spherical equivalent and cylinder for 1 year prior to implantation). 	

4. The Visian® TICL is intended for placement in the posterior chamber (ciliary sulcus) of the phakic eye.

Manufacturer	STAAR Surgical Company
Number	P030016/S001
Filing Date	5/8/2006
Approval Date	9/13/2018
Youngest Suggested Pediatric Subpopulation:	21 to 45 years of age
Exempt from User Fees because intended solely for pediatric use?	No
FDA Days	3053
Total Elapsed Days	4511

RECELL AUTOLOGOUS CELL HARVESTING

The RECELL® Autologous Cell Harvesting Device is indicated for the treatment of acute thermal burn wounds in patients 18 years of age and older. The RECELL® Device is used by an appropriately-licensed healthcare professional at the patient's point-of-care to prepare autologous Regenerative Epidermal Suspension (RES™) for direct application to acute partial-thickness thermal burn wounds or application in combination with meshed autografting for acute full-thickness thermal burn wounds.

Manufacturer	Avita Medical Americas, LLC
Number	BP170122
Filing Date	9/28/2017
Approval Date	9/20/2018
Youngest Suggested Pediatric Subpopulation:	18 years and older
Exempt from User Fees because intended solely for pediatric use?	No/ Small Business exempt
FDA Days	179
Total Elapsed Days	357

VII. Appendix B

Table 1. Total PMA and HDE Approvals and PMA and HDE Approvals With a Pediatric Indication from FY 2008 to FY 2018 (per Center).⁵⁰

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%)

⁵⁰ All the numbers have been updated to include devices approved by CBER, in addition to CDRH, with pediatric indications.

Table 2. PMA and HDE Approvals Indicated for Pediatric Subpopulations by Age from FY 2013 to FY 2018.

In Table 2, the devices were categorized by the youngest age for which there was an indication for use.⁵¹

Year/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

⁵¹ All the numbers have been updated to include devices approved by CBER, in addition to CDRH, with pediatric indications.