November 1, 2022

Diagnostic Grifols, S.A.
Elvira Estapé
Passeig Fluvial, 24
Parets del Valles
Barcelona, Spain 08150

Re:

STN	Trade/Device Name
BK220751	Erytra
BK220752	Erytra Eflexis
BK220753	DG Reader Net
BK220754	DG Gel 8 Neutral

Regulation Number:	21 CFR 864.9175
Regulation Name:	Automated Blood Grouping and Antibody Test System
Regulatory Class:	Class II
Product Code:	KSZ
Dated:	August 3, 2022
Received:	August 3, 2022

Dear Elvira Estapé:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market these devices, subject to the general controls provisions of the Act. Although this letter refers to your products as a devices, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your devices are classified (see above) into either class II (Special Controls) or class III (PMA), they may be subject to additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In

addition, FDA may publish further announcements concerning your devices in the **Federal Register**.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act, or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Orieji Illoh, MD
Director
Division of Blood Components and Devices
Office of Blood Research and Review
Center for Biologics Evaluation and Research

Enclosure
Indications for Use

Indications for Use

510(k) Number: BK220751

Device Name: Erytra

Indications for Use:

The Erytra is a fully-automated high-throughput analyzer designed to automate in vitro immunohematological testing of human blood utilizing DG Gel 8 card technology, including Blood Grouping, Antigen Typing, Antibody Screening, Antibody Identification, Antibody Titration, Compatibility Tests, and Direct Antiglobulin Tests.

As a standalone analyzer or interfaced to the customer's Laboratory Information System (LIS), the Erytra automates test processing functions and data management requirements using DG Gel 8 cards and digital image processing.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CBER, Office of Blood Research and Review (OBRR)

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Division Sign-Off
Office of Blood Research and Review

Indications for Use

510(k) Number: BK220752

Device Name: Erytra Eflexis

Indications for Use:

Erytra Eflexis is a fully-automated analyzer designed to automate in vitro immunohematological testing of human blood utilizing DG Gel 8 cards technology, including Blood Grouping, Antigen Typing, Antibody Screening, Antibody Identification, Antibody Titration, Compatibility Tests, and Direct Antiglobulin Tests.

As a standalone analyzer or interfaced to the customer's Laboratory Information System (LIS), Erytra Eflexis automates test processing functions and data management requirements using DG Gel 8 cards and digital image processing.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Indications for Use

510(k) Number: BK220753

Device Name: DG Reader Net

Indications for Use:

DG Reader Net is a device designed to read, interpret, and report the results of the processed DG Gel 8 cards. The instrument also identifies DG Gel 8 cards by reading their barcodes.

As a stand-alone or interfaced to the customer's Laboratory Information System (LIS), the instrument automates data management requirements using DG Gel 8 cards and digital image processing.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Indications for Use

510(k) Number: BK220754

Device Name: DG Gel 8 Neutral

Indications for Use:

The DG Gel 8 Neutral card is for the detection of antibodies to red blood cell antigens of human blood samples and for its use as a control microtube.
For use with the DG Gel System.
For in vitro diagnostic use.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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