



January 18, 2018

Grifols Diagnostic Solutions, Inc.
Attention: Camilla Kuanghui Lu, PhD
4560 Horton Street
Emeryville, CA 94608

Re: BK170162
Device Name: Procleix Xpress® System (Software v3.0)
Regulation Number: 21 CFR 864.9175
Regulation Name: Automated blood grouping and antibody test system
Regulatory Class: II
Product Code: MMH
Dated: January 18, 2018
Received: January 18, 2018

Dear Dr. Lu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to a legally marketed predicate device 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 the device, subject to the general controls provisions of the Act. 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 device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device 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 device complies 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 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS)

regulation (21 CFR Part 820); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Hira L. Nakhasi, PhD
Director
Division of Emerging and
Transfusion Transmitted Diseases
Office of Blood Research and Review
Center for Biologics Evaluation and Research

Enclosure
Indications For Use

Indications for Use

510(k) Number: BK170162

Device Name: MMH

Indications for Use:

The Procleix Xpress® System (Software and Instrument) is intended to be used to create pools of human plasma or serum for blood screening tests for viral nucleic acids. The Procleix Xpress® System automatically transfers plasma or serum from individual samples into a single master pool tube, which may be used for further testing in Procleix® systems. The Procleix Xpress® System also collects barcode data from all tubes, racks, and archive plates used in a given pooling run, establishing positive specimen identification and Master Pool Tube (MPT) composition. In addition, the Procleix Xpress® System can be used to dispense human plasma or serum aliquots into an archive plate.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CBER, Office of Device Evaluation (ODE)

Division Sign-Off, Office of Blood Research and Review