August 1 , 2019

Newmarket Biomedical Ltd.
Attention: Mr. Colin Knox
Unit 1 Lanwades Business Park
Kentford, Suffolk
United Kingdom
CB8 7PN

Re:	BK180301
Device Name:	PK7400 TP HA Controls PK7400 TP HA Reagent
Regulation Number:	21 CFR 866.3830
Regulation Name:	Treponema pallidum treponemal test reagents
Regulatory Class:	II
Product Code:	MYR, GMR
Dated:	July 31, 2019
Received:	July 31, 2019

Dear Mr. Knox:

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. Although this letter refers to your product as a device, 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 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 801and 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).

If you have questions about this letter, please contact Cherry Geronimo, Regulatory Project Manager, at (240) 402-9555 or cherry.geronimo@fda.hhs.gov.

Sincerely,

Hira L. Nakhasi, PhD
Director
Divison 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: BK180301

Device Name: PK7400 TP HA Controls
PK7400 TP HA Reagent

Indications for Use:

PK7400 TP HA REAGENT is intended for the qualitative screening of blood and plasma donors for the detection of *Treponema pallidum* IgG and IgM antibodies to syphilis in human serum, EDTA plasma or CPDA plasma using the Beckman Coulter PK7400 Automated Microplate System.

This assay is not intended for diagnostic use.

PK7400 TP HA CONTROLS are intended for use with the PK7400 TP HA REAGENT for the qualitative screening of blood and plasma donors for the detection of *Treponema pallidum* IgG and IgM antibodies to syphilis in human serum, EDTA plasma or CPDA plasma using the Beckman Coulter PK7400 Automated Microplate System.

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

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CBER, Office of Blood Research and Review (OBRR)

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Division Sign-Off, OBRR