SUBSTANTIALLY EQUIVALENT
December 14, 2017

Baxalta US, Inc.
Attention: Daphne King
Manager, Global Regulatory Affairs
One Baxter Way
Westlake Village, CA 91362

Re: BK170028
Trade/Device Name: myPKFiT for ADVATE
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive pulmonary-function value calculator
Regulatory Class: Class II
Common Name: Sparse sample PK profile and dosing software
Product Code: PHY
Dated: November 15, 2017
Received: November 16, 2017

Dear Ms. King:

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 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 (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. Please note: CBER does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 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,

Wilson W. Bryan, MD
Director
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research

Enclosure
Indications for Use

Indications for Use (CBER/OTAT)

510(k) Number: BK170028

Device Name: myPKFiT for ADVATE

Indications for Use:

The myPKFiT for ADVATE software is intended for use by licensed healthcare professionals (HCPs) who are familiar with hemophilia care. myPKFiT for ADVATE can be used to generate ADVATE dosage and frequency recommendations for routine prophylaxis for an individual patient 16 years of age or older and body weight of 45kg or greater, using that patient's age and body weight information and local laboratory FVIII one-stage clotting activity measurements of sparse samples collected from that patient. A minimum of two sparse sampling points are required at the recommended 3-4 hours (± 30 minutes) and at 24-32 hours (±1 hour) post-infusion.

HCPs will also be able to evaluate various prophylaxis dose regimens tailored to an individual patient's needs and treatment plan. The software output may be used to guide decisions on appropriate ADVATE dose and infusion intervals to maintain FVIII activity levels at or above a user-specified minimum FVIII activity level between 1% to 3% above natural baseline for an individual patient in accordance with FDA approved dosing recommendations provided in the ADVATE Prescribing Information (PI).

myPKFiT for ADVATE should only be used to evaluate prophylactic dosing regimens for hemophilia A patients treated with ADVATE, as per the ADVATE PI. myPKFiT for ADVATE is not indicated for the treatment of von Willebrand disease. myPKFiT for ADVATE should not be used for patients who have developed neutralizing antibody (inhibitor) to FVIII products.

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 THIS LINE- CONTINUE ANOTHER PAGE IF NEEDED)

Concurrence of CBER, Office of Tissues and Advanced Therapies

_____
Office Sign-Off
Office of Tissues and Advanced Therapies

510(k):__BK170028__