



510(k) Summary

DATE SUMMARY PREPARED:

13 December 2017

OWNER:

Baxalta US Inc.
One Baxter Way
Westlake Village, CA 91362

PRIMARY CONTACT PERSON:

Daphne C. King, MT, MS
Manager, Regulatory Affairs CMC Devices
One Baxter Way
Westlake Village, CA 91362
Telephone: (805) 372-3068
Fax: (805) 372-3052

SECONDARY CONTACT PERSON:

Aimee Greco, MSRSc, MSRA
Director, Regulatory Affairs CMC Devices
One Baxter Way
Westlake Village, CA 91362
Telephone: (805) 372-3080
Fax: (805) 372-3052

IDENTIFICATION OF THE DEVICE:

Trade Name or Proprietary Name: myPKFiT for ADVATE
Common Name: Sparse Sample PK Profile and Dosing Software
Classification Name: Predictive Pulmonary-Function Value Calculator
Classification: 21 CFR 868.1890
Class: Class II
Product Code: PHY

PREDICATE DEVICE:

The predicate device is listed in [Table 1](#) below.

Table 1. Primary Predicate Device

Device	Company	Predicate 510(k)	Clearance Date
TrxF Intelligent Dosing System	The RxFiles Corporation	K011571	9 August 2001

DEVICE DESCRIPTION

myPKFiT for ADVATE is a web-based application that allows authorized users to simulate dosing regimens using individualized patient Pharmacokinetic (PK) profiles.

myPKFiT for ADVATE uses FVIII activity above a user specified threshold to guide physicians' decisions on the frequency of dosing and appropriate dosing amount.

myPKFiT for ADVATE consists of the following functions:

- User Management – enables authorized users to create and manage user accounts for HCPs in their clinic / treatment center.
- Patient Management – enables HCPs to create and maintain patient records.
- Assessments – enable HCPs to create individualized patient PK profiles using local FVIII laboratory data.
- Dosing Calculation – enables HCPs to simulate FVIII dosing schedules.

There is no direct interface between myPKFiT for ADVATE and the patient. The individual patient files will be encrypted and stored on a third party central data storage server.

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 (\pm 30 minutes) and at 24-32 hours (\pm 1 hour) post-infusion.