oneFIT medical
% Ms. Camille Vernay
QA / RA Manager
18 Rue Alain Savary
25000 Besancon
FRANCE

April 27, 2018

Re: K173390
Trade/Device Name: hipEOS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 16, 2018
Received: March 19, 2018

Dear Ms. Vernay:

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: CDRH 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 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,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
/ K173390

Device Name
hipEOS

Indications for Use *(Describe)*
hipEOS software is indicated to be used for assisting healthcare professionals in preoperative planning of total hip arthroplasty (THA). The software allows for overlaying of 3D/2D hip implant models on radiological images or 3D reconstruction of bone, and includes tools for performing measurements on the image or 3D model of bones and for selecting and positioning the hip implant models. Clinical judgments and experience are required to properly use the software.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

oneFIT medical's hipEOS

Submitter

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Contact Person: Ms Camille VERNAY, QA/RA Manager

Date Prepared: March 16th, 2018

Device:

Name of Device: hipEOS
Classification Name: Picture Archiving and Communication System (21 CFR 892.2050)
Regulatory Class: II
Product Code: LLZ

Predicate Devices

Primary predicate: **hipEOS 2.5** (K161479) by oneFIT medical
Second predicate: **DYONICS PLAN Hip Impingement Planning System** (K132636) by Smith & Nephew, Inc.

Device Description

hipEOS 3.0 allows surgeons to perform preoperative surgical planning of hip surgeries in case of Total Hip Arthroplasty (THA). The software provides surgical tools for the implantation of a Total Hip Prosthesis. This software can be used to plan interventions using implants from different manufacturers. The images displayed are x-rays from EOS System (EOS Imaging) and 3D model of the hip from sterEOS Workstation (EOS Imaging). hipEOS also displays preoperative parameters and updated values of parameters after planning. It exports a planning report containing the planning parameters: model, size and position of implants. hipEOS is accessible on any computer via ONEFIT Management System (Class I device - Product code LMD – 510(k) Exempt) that provides a secure internet interface and storage through authentication mechanisms.

Intended Use / Indications for Use

hipEOS software is indicated to be used for assisting healthcare professionals in preoperative planning of total hip arthroplasty (THA). The software allows for overlaying of 3D/2D hip implant models on radiological images or 3D reconstruction of bone, and includes tools for performing

measurements on the image or 3D model of bones and for selecting and positioning the hip implant models. Clinical judgments and experience are required to properly use the software.

Comparison of Technological Characteristics with the predicate devices

Preoperative planning for hip surgery is the technological principle for both hipEOS and its predicate devices. The aim for these software is to provide to the surgeon realistic tools for performing the preoperative planning of hip surgeries.

At a high level, the subject and its predicate devices are based on the following same technological elements:

- Access to the software is limited only to surgeons because surgical experience is required.
- Use of 2D images and 3D model of the hip.
- Use of the workflow to guide the surgeon through the steps of planning: observation, analysis and action.
- An interface that allows for the maximum amount of information (including images) and tools, visible simultaneously on the same page.
- Display values of preoperative parameters and updated values after planning.

The following technological differences exist between the subject and its predicate devices:

(1) Use of seated patient images, if available

They are optional in hipEOS 3.0 and they can be used to provide more information to the surgeon (ROM simulation in sitting and theoretical sitting). This difference does not raise new questions of safety or performance for hipEOS 3.0 because this type of imagery was already used by the primary predicate.

(2) Workflow available

The appearance of steps in hipEOS 3.0 is related to the decomposition of the planning to ensure that the user will not confuse the preoperative information with those from the planning and also to simplify the interface by minimizing the information present at each step. This difference does not raise new questions of safety or performance for hipEOS 3.0 because the user still has the same information at his disposal.

(3) The range of motion simulation

This type of analysis tool has already been integrated with planning software for total hip arthroplasty (predicate 2). Although the range of motion of the predicate 2 and the one of the submitted device are different, it does not raise new questions of safety or performance for hipEOS 3.0: the ROM of hipEOS 3.0 allows to evaluate for each planning the risk of collision between the components of the implant. This feature is only based on objects of which the 3D geometry is accurate.

(4) The generation of a second planning report, in DICOM format

This difference does not raise new questions of safety or performance for hipEOS 3.0 because the information in the planning report was already provided to the user and the chosen format is universal.

Performance Data

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". The software was considered as a "moderate" level of concern, since a failure or latent design flaw could directly result in minor injury to the patient or operator, or could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider.

Conclusions

The device has the same intended use, and similar indications for use, technological characteristics, and principles of operation as its predicate device. The minor differences between the device and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the hipEOS 3.0 is as safe and effective as its predicates hipEOS 2.5 (K161479) and DYONICS PLAN Hip Impingement Planning System (K132636) and, thus, is substantially equivalent.