DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 28, 2016

ONEFIT Medical
% Mr. Julien Simon
QA / RA Manager
18 rue Alain Savary
BESANCON 25000
FRANCE

Re: K161479
Trade/Device Name: hipEOS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 27, 2016
Received: May 31, 2016

Dear Mr. Simon:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K161479

Device Name
hipEOS

Indications for Use *(Describe)*

hipEOS is indicated for assisting healthcare professionals in preoperative planning of hip replacement surgery. The software allows for overlaying of 3D/2D implant models on radiological images and 3D reconstruction of bone, and includes tools for performing measurements on the image and 3D model of bones and for selecting and positioning the implant model. 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's hipEOS

Submitter

ONEFIT medical, Inc.
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Contact Person: Mr. Julien SIMON, QA/RA Manager
Date Prepared: May 27th, 2016

Device

Trade name: hipEOS
Common or Usual Name: ONEFIT Hip Planner
Classification Name: Picture Archiving and Communication System (21 CFR 892.2050)
Regulatory Class: II
Product Code: LLZ

Predicate Device

ONEFIT Hip Planner (K142671) by ONEFIT medical.

Intended Use/Indications for Use

hipEOS is indicated for assisting healthcare professionals in preoperative planning of hip replacement surgery. The software allows for overlaying of 3D/2D implant models on radiological images and 3D reconstruction of bone, and includes tools for performing measurements on the image and 3D model of bones and for selecting and positioning the implant model. Clinical judgments and experience are required to properly use the software.

Device Description

hipEOS allows surgeons to perform pre-operative surgical planning for hip replacement. The program features an extensive regularly updated library of digital 3D models of implants form leading implant manufacturers. It allows the overlay of the 3D/2D implant models on the radiological images and on the 3D reconstruction and permits the selection of appropriate size and position of implant. hipEOS is accessible on any computer via ONEFIT Management System that provides secure internet interface through authentication mechanisms, web accessible authentication servers and access for authorized users through secure protocols to web server.

Comparison of Technological Characteristics with the predicate device

The technological characteristics of the modified hipEOS are essentially identical to the cleared ONEFIT Hip Planner (K142671).The main differences with the cleared ONEFIT Hip Planner consist of the following minor modifications:

- Integration of prosthesis with modular neck.
- Online validation of the 3D modeling and landmarks positioning by the surgeon.

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 similar intended uses and indications, technological characteristics, and principles of operation as its predicate device. The minor differences between the device and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that hipEOS is as safe and effective as the company's cleared ONEFIT Hip Planner device and, thus, is substantially equivalent.