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

ONEFIT medical, Inc.
% Mr. Julien Simon
QA/RA Manager
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FRANCE

October 3, 2016

Re: K161828
Trade/Device Name: kneeEOS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 29, 2016
Received: August 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,

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)*
K161828

Device Name
kneeEOS

Indications for Use *(Describe)*
kneeEOS is a software indicated for assisting orthopedic surgeon in preoperative planning of knee orthopedic surgery. The software allows for overlaying of 3D/2D implants models on radiological images EOS based and 3D reconstruction of bones, and includes tools for performing measurements on the images or 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 kneeEOS

Submitter

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Contact Person: Mr Julien SIMON, QA/RA Manager
Date Prepared: June 30, 2016

Device

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

Predicate Device

TraumaCad Release 2.0 (K073714) by ORTHOCRAT LTD.

Intended Use/Indications for Use

kneeEOS is a software indicated for assisting orthopedic surgeon in preoperative planning of knee orthopedic surgery. The software allows for overlaying of 3D/2D implants models on radiological images EOS based and 3D reconstruction of bones, and includes tools for performing measurements on the images or 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

kneeEOS 1.0 allows surgeons to perform preoperative surgical planning of total knee arthroplasties. The software provides surgical tools to analyze preoperative data, to set the resection levels, to position and size the femoral and tibial components and to evaluate the final alignment of the leg. The images displayed are x-rays from EOS System (K152788) and 3D model of the knee from sterEOS Workstation (K160914). kneeEOS also displays preoperative parameters and updated values of these parameters after planning. kneeEOS 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.

Comparison of Technological Characteristics with the predicate device

Preoperative planning for knee surgery is the technological principle for kneeEOS and one of the possibilities offered by the predicate. The aim for these software is to provide to the surgeon realistic tools for simulating total knee arthroplasty.

kneeEOS 1.0 (ONEFIT medical, Inc.) and its predicate TraumaCad 2.0 (Orthocrat, Ltd.) are based on the same following technological elements:

- Access to the software is secured and limited only to surgeons because personal data are stored in those software and surgical experience is required.
- Use of x-ray images and preoperative parameters calculated from the patient's anatomy.
- 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.
- Tools for improve visualization, to perform measurements, to choose, size and position implants, and to adjust the alignment of the leg.
- Display values of preoperative parameters and updated values after planning.

The only differences between kneeEOS and its predicate are:

(1) kneeEOS claims compliance with standards EN ISO 14971:2012, IEC 62304:2006 and EN 62366:2008.
(2) Software and hardware minimum requirements for kneeEOS.
(3) kneeEOS input data comprise a 3D model of the knee.
(4) kneeEOS exports a PDF planning report.
(5) kneeEOS displays preoperative and planned values of parameters.

These differences do not present any new questions of safety or effectiveness because:

(1) These international standards are or have been recognized by the FDA. The standard on ability has recently been replaced by a new version, currently recognized by the FDA. However, the two versions claim similar principles on the development of the interface. Despite the lack of information on the subject for the predicate, there is no safety or efficiency question created by this difference, because these standards have also been used in the development of the latest FDA-approved software of ONEFIT medical: spineEOS (see Appendix [42] K160407_spineEOS). These three standards are intended to help reduce risk and errors in the software design.
(2) These requirements are not disproportionate to the computers currently on the market.
(3) This 3D model reconstruction is performed by sterEOS Workstation (K160914), which is a medical device already cleared by the FDA. All indications of use and operating procedures of sterEOS Workstation are respected. The software kneeEOS uses the sterEOS Workstation output data as input data without any prior modification.
(4) Both software allow to generate a report which contains all data from the planning. The difference lies in the format of generated reports (PDF/HTML): Most web browsers up to date include a PDF Reader and this format has the advantage of being more protected against any changes that HTML page. This difference does not raise questions about safety or effectiveness in comparison to TraumaCad. All the information contained in this report can be found in the software. The generation of a planning report is also an available feature in kneeEOS (K160407).

(5) TraumaCad does not have distinct preoperative / planned steps; images are simply displayed and the user can perform measurements on the x-rays (preoperative measurements) or on templates superimposed on x-rays (planned parameters). In kneeEOS, these values (preoperative and after planning) are automatically displayed in the left column and on the x-rays but the same information can be extracted from both software. These differences do not raise questions about safety or effectiveness in comparison to TraumaCad because kneeEOS measurements are calculated from anatomical points, which are positioned with sterEOS Workstation (K160914).

kneeEOS has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the kneeEOS and its predicate device raise no new issues of safety or effectiveness.

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 kneeEOS is as safe and effective as its predicate TraumaCad Release 2.0 (K073714) and, thus, is substantially equivalent.