



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
18 rue Alain Savary
Besancon, 25000
FRANCE

April 8, 2016

Re: K160407
Trade/Device Name: spineEOS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 12, 2016
Received: February 16, 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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned above the typed name and title.

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

Indications for Use

510(k) Number (if known)

/ K160407

Device Name

spineEOS

Indications for Use (Describe)

Using 3D data and models obtained with sterEOS workstation, spineEOS software is indicated for assisting healthcare professionals in viewing, measuring images as well as in preoperative planning of spine surgeries. The device includes tools for measuring spine anatomical components for placement of surgical implants. Clinical judgment and experience are required to properly use the software online.

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 spineEOS**

Submitter

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Contact Person: Mr Julien SIMON, QA/RA Manager
Date Prepared: February 11, 2016

Device

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

Predicate Device

Surgimap 2.0 (K141669) by Nemaris Inc.

Intended Use/Indications for Use

Using 3D data and models obtained with sterEOS workstation, spineEOS software is indicated for assisting healthcare professionals in viewing, measuring images as well as in preoperative planning of spine surgeries. The device includes tools for measuring spine anatomical components for placement of surgical implants. Clinical judgment and experience are required to properly use the software online.

Device Description

spineEOS 1.0 allows surgeons to perform preoperative surgical planning of spine surgeries in case of Adolescent Idiopathic Scoliosis (AIS) or deformative/degenerative spine. The software provides surgical tools for the correction of the curvature, for the placement of cages and for the achievement of osteotomies. The images displayed are x-rays from EOS System (K152788) and 3D model of the spine from sterEOS Workstation (K141137). spineEOS also displays preoperative parameters compared with reference values and updated values of parameters after planning. spineEOS 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 spine surgery is the technological principle for both spineEOS and its predicate. The aim for these software is to provide to the surgeon realistic tools for simulating the correction of the curves of the spine.

spineEOS 1.0 (ONEFIT medical, Inc.) and its predicate Surgimap 2.0 (Nemaris, Inc.) 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 calculated parameters 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 angle measurements, to position cages, osteotomies and to adjust the curvature of the spine.
- Display values of preoperative parameters and updated values after planning.

The only differences between spineEOS and its predicate are:

- (1) spineEOS claims compliance with the standard IEC 62366-1:2015.
- (2) spineEOS is available online.
- (3) Software and hardware minimum requirements for spineEOS.
- (4) spineEOS allows to export a planning report.
- (5) X-rays for spineEOS are already calibrated.
- (6) spineEOS input data comprise a 3D model of the spine.

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

- (1) This standard is about the application of the concept of usability for medical devices interface. This standard helps the manufacturer to take into account the dangers associated with the interface and reduce the risks associated with the use as far as possible.
- (2) Data storage and transfers are secured with currently available technologies. Moreover, ONEFIT can ensure that all users have access to the latest version of software by managing updates and the availability. This feature is also encountered in the ONEFIT Hip Planner (K142671).
- (3) These requirements are not disproportionate to the computers currently on the market.
- (4) All the information contained in this report can be found in the software, which is equivalent to the consult of a saved planning in Surgimap. The generation of a planning report is also an available feature in the ONEFIT Hip Planner (K142671).
- (5) X-rays come from EOS System (K152788) and data for calibration are recorded during the acquisition of the images to calibrate them automatically. spineEOS only import the output data unchanged. The risk of human error regarding the calibration images is thus rejected.
- (6) This 3D model reconstruction is performed by sterEOS Workstation (K141137), which is a medical device already cleared by the FDA. All indications of use and operating procedures of sterEOS Workstation are respected. spineEOS only import the output data unchanged.

spineEOS has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the spineEOS 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 spineEOS is as safe and effective as its predicate Surgimap 2.0 (K141669) and, thus, is substantially equivalent.