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

Medtronic Sofamor Danek USA, Inc.
% Ms. Lila Joe
Principal Regulatory Affairs Specialist
1800 Pyramid Place
MEMPHIS TN 38132

May 22, 2015

Re: K142648
Trade/Device Name: SPINEDESIGN™ Spine Surgery Planning
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 28, 2015
Received: April 29, 2015

Dear Ms. Joe:

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 A Ochs

Robert Ochs, Ph.D.
Acting 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)*

K142648

Device Name

SPINEDESIGN™ Spine Surgery Planning

Indications for Use *(Describe)*

The SPINEDESIGN™ Spine Surgery Planning application is a mobile medical application to assist healthcare professionals in planning orthopedic surgeries. The device allows service providers to perform spine related measurements of the images in the preoperative planning of orthopedic spinal surgery and includes tools for measuring anatomical components for placement of surgical implants. Clinical judgment and experience are required to properly use the software. This software is for orthopedic planning only; not for primary image viewing.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Medtronic Sofamor Danek USA, Inc.
SPINEDESIGN™ Spine Surgery Planning

May 21, 2015

I. SUBMITTER:

Medtronic Sofamor Danek, USA Inc.
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Contact Person:
Lila Joe
Principle Regulatory Affairs Specialist
Telephone: (901) 399-3248

Date Prepared: May 21, 2015

II. DEVICE:

Name of Device:	SPINEDESIGN™ Spine Surgery Planning
Common or Usual Name:	Picture archiving and communications system (21 CFR 892.2050)
Classification Name:	System, Image Processing, Radiological
Regulatory Class:	Class II
Product Code:	LLZ

III. PREDICATE DEVICE:

Nemaris, Inc., Surgimap Spine (K111019, SE 9/30/2011)
This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION:

SPINEDESIGN™ Spine Surgery Planning is a preoperative planning tool that allows surgeons to determine measurements from patient radiographs and plan spinal surgery. The SPINEDESIGN™ Spine Surgery Planning application is compatible with the off-the-shelf Apple® iPad® and functions as an image communications and storage device. The subject software application is designed for iOS 6.0 and higher versions, on iPad® 2, or newer devices, and uses several standard frameworks through Xcode.

For Adolescent Idiopathic Scoliosis (AIS) cases, the software application will also determine the Lenke classification based on the patient's measurements, and allow the surgeon to enter the Risser grade into the application. At a high level, the SPINEDESIGN™ Spine Surgery Planning application is a pre-surgical planning tool that provides surgeons an additional method for performing measurements and planning spinal surgeries by uploading radiographs and performing calculations at his/her convenience. SPINEDESIGN™ Spine Surgery Planning application is not intended for diagnostic purposes.

V. INDICATIONS FOR USE:

The SPINEDESIGN™ Spine Surgery Planning application is a mobile medical application to assist healthcare professionals in planning orthopedic surgeries. The device allows service providers to perform spine related measurements of the images in the preoperative planning of orthopedic spinal surgery and includes tools for measuring anatomical components for placement of surgical implants. Clinical judgment and experience are required to properly use the software. This software is for orthopedic planning only; not for primary image viewing.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

The SPINEDESIGN™ Spine Surgery Planning application uses similar fundamental technology as the predicate Surgimap Spine Software (K111019, SE 9/30/2011). Both the subject and predicate devices are computer software applications that use algorithms to take measurements from uploaded patient radiographs and allow the surgeon to use this information to plan patient spinal surgery. The subject application differs from predicate application in that the subject application has a smaller display screen, a touch screen input, has fewer connectivity options, and is mobile.

VII. PERFORMANCE DATA:

The following performance data were provided in support of the substantial equivalence.

Biocompatibility Testing:

The subject SPINEDESIGN™ Spine Surgery Planning is a software application that is downloaded from a web portal onto an Apple® iPad®. The subject SPINEDESIGN™ Spine Surgery Planning application is intended to be used by the surgeon to perform calculations and plan patient surgery. Therefore, the software application is not expected to come in contact with the patient.

According to the following documents:

- FDA's blue book memorandum #G95-1, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing",

- FDA's Draft Guidance for Industry and Food and Drug Administration Staff, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing", released for comment on April 23, 2013, and
- Attachment C from both documents listed above, "Biocompatibility Flow Chart for the Selection of Toxicity Tests for 510(k)s",

a device that does not contact the body directly or indirectly (non-patient contacting medical device) does not require biocompatibility testing. The biocompatibility requirement has been met.

Electrical Safety and Electromagnetic Compatibility (EMC):
EMC testing was not required for this submission.

Software Verification and Validation Testing:
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 or Premarket Submission for Software Contained in Medical Devices." Medtronic believes the level of concern for the subject SPINEDESIGN™ Spine Surgery Planning application to be "**moderate**" since failures or latent flaws are unlikely to cause any injury to the patient or the operator.

Software Verification and Validation Testing included the following tests:

- Traceability Matrix
- Software validation testing, including code review
- User Acceptance Testing (UAT)
- Predicate to Subject Measurement Comparison Test

All verification and validation testing met the predetermined acceptance criteria.

Mechanical and Acoustic Testing:

Mechanical and Acoustic testing were not required for this submission.

Animal Study:

Animal testing was not required for this submission.

Clinical Studies:

Clinical studies were not required for this submission.

VIII. CONCLUSIONS:

Software verification and validation testing demonstrates that the SPINEDESIGN™ Spine Surgery Planning application does not raise any new questions of safety and efficacy as compared to the predicate, Surgimap Spine (K111019, SE 9/30/2011). Therefore, Medtronic believes the SPINEDESIGN™ Spine Surgery Planning application is substantially equivalent to the predicate, Surgimap Spine.