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

August 12, 2016

Medtronic Sofamor Danek
Mr. Ankit Shah
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K161210
Trade/Device Name: RIALTO™ SI Fusion System, MEDTRONIC RESUSABLE INSTRUMENTS FOR USE WITH IPC™ POWEREASE™ SYSTEM, MEDTRONIC NAVIGATED MANUAK REUSABLE INSTRUMENTS FOR USE WITH THE STEALTHSTATION™ AND IPC™ POWEREASE™SYSTEMS
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: OUR, OLO, HWE
Dated: July 29, 2016
Received: August 1, 2016

Dear Mr. Shah:

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 Parts 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" (21CFR 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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K161210

Device Name
RIALTO™ SI Fusion System

Indications for Use *(Describe)*
The RIALTO™ SI Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*
K161210

Device Name
MEDTRONIC REUSABLE INSTRUMENTS FOR USE WITH THE IPC™ POWEREASE™ SYSTEM

Indications for Use *(Describe)*
IPC™ System is indicated for the incision/cutting, removal, drilling and sawing of soft and hard tissue and bone, and biomaterials in Neurosurgical (Cranial, Craniofacial), Orthopedic, Arthroscopic, Spinal, Sternotomy, and General surgical procedures.

The IPC™ POWEREASE™ System is indicated for drilling, tapping and driving screws and working end attachments during spinal surgery, including open and minimally invasive procedures. It is also used in placement or cutting of screws, posts and rods.

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)

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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)*
K161210

Device Name
MEDTRONIC NAVIGATED MANUAL REUSABLE INSTRUMENTS FOR USE WITH THE STEALTHSTATION™ AND IPC™ POWEREASE™ SYSTEMS

Indications for Use *(Describe)*
Medtronic Navigated Reusable Instruments are intended to be used during the preparation and placement of Medtronic screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open, or minimally invasive, procedures. Medtronic Navigated Reusable Instruments are specifically designed for use with the StealthStation™ System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra can be identified relative to a CT or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy. Medtronic Navigated Reusable Instruments are also compatible with the IPC™ POWEREASE™ System.

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)

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RIALTO™ SI Fusion System

510(k) SUMMARY

July 2016

I. Submitter

Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132
(901)396-3133

Contact Ankit K. Shah
Senior Regulatory Affairs Specialist

Date Prepared July 28, 2016

II. Device

Name of Device RIALTO™ SI Fusion System, Medtronic Reusable Instruments for Use with the IPC™ Powerease™ System, and Medtronic Navigated Manual Reusable Instruments for use with the StealthStation™ and IPC™ Powerease™ Systems

Common Name Smooth or threaded metallic bone fixation fastener (Implant)
Taps, Drivers and Drills (Instrument)

Classification Name Sacroiliac Joint Fixation - OUR
(For Implant)

Stereotaxic Instrument - OLO
(For Navigated Instruments)

Surgical Instrument Motors and Accessories/Attachments - HWE

(For Instruments Compatible with the IPC® POWEREASE® System)

Classification Class II (Implant and Instruments)

Product Codes

OUR (Implants)
21 CFR 888.3040
OLO (Navigated Instruments)
21 CFR 882.4560

HWE (IPC® POWEREASE® Compatible Instruments)
21 CFR 878.4820

Predicates There are 6 Predicates.

MSB Sacroiliac Joint Fusion Device
K110472, S.E. 05/29/2012 (Primary Predicate)

iFuse Implant System
K131405, S.E. 10/16/2013

IPC® POWEREASE® System
K111520, S.E. 10/26/2011

Navigated CD Horizon Solera Screwdriver/Taps
K140454, S.E. 05/22/2014

Navigated CD HORIZON® SOLERA™ Screwdrivers, CD HORIZON® SOLERA™ Taps, CD HORIZON® SOLERA™ Iliac Taps, CD HORIZON® LEGACY™ Taps
K124004, S.E. 03/22/2013

Navigated Disc Prep Instruments and CAPSTONE Trials
K150231, S.E. 06/16/2015

The predicates have not been subject to a design related recall.

III. Product Description

RIALTO™ SI Fusion System

The subject RIALTO™ SI Fusion System consists of cannulated devices available in various lengths, used to provide stabilization when fusion of the sacroiliac joint is desired. Autograft and/or allograft may be placed in conjunction with the RIALTO™ SI Fusion System. The RIALTO™ implant are made using Titanium Alloy and are 40mm-60mm in length with a diameter of 12mm. This device may be implanted via a minimally invasive approach using fluoroscopy or navigated instruments compatible with Medtronic StealthStation® and IPC® POWEREASE®.

Medtronic Reusable Instruments Only Compatible with the IPC® POWEREASE® System

The subject Medtronic Reusable Taps, Drivers and Drills are spine preparation instruments made of high grade stainless steel and are designed specifically for subject RIALTO™ SI Fusion System. The subject Taps, Drivers and Drills are compatible with Medtronic's IPC® POWEREASE® System may be connected to the IPC® POWEREASE® handpiece. The subject Taps, Drivers and Drills can be used manually using existing Medtronic Class I Exempt quick connect handles in place of the IPC® POWEREASE® handpiece.

Medtronic Reusable Instruments Compatible with the STEALTHSTATION® System and IPC® POWEREASE® System

The subject Medtronic Navigated Reusable Taps, Drivers and Drills are spine preparation instruments made of high grade stainless steel. These instruments were specifically designed for use with subject RIALTO™ SI Fusion System in procedures where the use of stereotactic surgery may be appropriate. The subject Taps, Drivers and Drills are also compatible with Medtronic's IPC® POWEREASE™ System when connected to the POWEREASE™ handpiece or may be used manually with existing Medtronic Class I Exempt quick connect handles in place of the IPC® POWEREASE® handpiece or the NavLock™ tracker.

IV. Indications for Use:

RIALTO™ SI Fusion System

The RIALTO™ SI Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

Medtronic Reusable Instruments For Use with the IPC® POWEREASE® System

IPC® System is indicated for the incision/cutting, removal, drilling and sawing of soft and hard tissue and bone, and biomaterials in Neurosurgical (Cranial, Craniofacial), Orthopedic, Arthroscopic, Spinal, Sternotomy, and General surgical procedures.

The IPC® POWEREASE® System is indicated for drilling, tapping and driving screws and working end attachments during spinal surgery, including open and minimally invasive procedures. It is also used in placement or cutting of screws, posts and rods.

Medtronic Navigated Reusable Instruments For Use with STEALTHSTATION® and IPC® POWEREASE™ Systems

Medtronic Navigated Reusable Instruments are intended to be used during the preparation and placement of Medtronic screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open, or minimally invasive, procedures. Medtronic Navigated Reusable Instruments are specifically designed for use with the StealthStation® System, which is indicated for any medical condition in which stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy. Medtronic Navigated Reusable Instruments are also compatible with the IPC® POWEREASE™ System.

V. Comparison of Technological Characteristics

The primary predicate for the RIALTO™ SI Fusion System is the predicate SI-FIX Sacroiliac Joint Fusion System K110472, S.E. 05/29/2012 (Primary Predicate).

The subject RIALTO™ SI Fusion System implants have the same or similar intended use, fundamental scientific technology, material, and indications as the following FDA cleared predicates K110472 (S.E. 05/29/2012) and K131405 (S.E. 10/16/2013).

The subject RIALTO™ SI Fusion System instruments have the same or similar intended use, fundamental scientific technology, material, and indications as the following FDA cleared predicates K111520 (S.E. 10/26/2011), K110472 (S.E. 05/29/2012), K140454 (S.E. 05/22/2014), K124004 (S.E. 03/22/2013) and K150231 (S.E. 06/16/2015)

VI. Performance Data

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

Biocompatibility

Identical to the primary predicate devices the implants in the subject RIALTO™ SI Fusion System are made using Titanium alloy.

The non-sterile instruments are manufactured using stainless steel and are identical to the materials used for the instruments cleared under predicate submissions.

The titanium alloy and stainless steel material used for the subject RIALTO™ SI Fusion System implants and instruments have a long clinical history of safe and effective use in similar commercially available medical devices. Therefore, no additional biocompatibility testing is required.

Mechanical Testing

In accordance with the *Guidance for Industry and FDA Staff - Spinal System 510(k)'s,* Medtronic has evaluated the subject devices to demonstrate substantial equivalence to the predicate devices.

Design verification testing for the subjectimplants was completed in accordance with

- ASTM F543-13 Standard Specification and Test Methods for Metallic Medical Bone Screws
- ASTM F2193-02 (2007) Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System

The tests completed were:

- Push-Out
- Torque–to-Fail
- Four Point Bend
- Shear Testing

The verification testing on the instruments included Navigation accuracy on the instruments compatible with StealthStation™ and IPC™ Powerease™.

The subject devices met the pre-determined acceptance criteria for all tests. Therefore, design verification testing determined that the subject screws and instruments are substantially equivalent to the predicate devices.

Design validation testing was performed that demonstrated that the subject instruments performed as intended and to validate the surgical approach.

Non-Pyrogenicity Endotoxin Testing

The bacterial endotoxin test, also known as Limulus Amebocyte Lysate (LAL) test, was performed utilizing worst case subject RIALTO™ SI Fusion implants to verify that the subject implants meet the 20 endotoxin units (EU)/device pyrogen limit specification. Testing was successfully performed and it was confirmed that the subject implants meet the 20 EU/device testing limit for general medical devices that are implanted as outlined in ANSI/AAMI ST72, Bacterial endotoxins – Test methods, routine monitoring, and

alternatives to batch testing and USP <161>, Transfusion and Infusion Assemblies and Similar Medical Devices.

VII. Conclusions

Based on the test results and additional supporting information provided in this pre-market notification, the subject devices demonstrated substantial equivalence to the legally marketed predicate devices.