



June 26, 2025

Medtronic Sofamor Danek USA, Inc.
Rong Guo
Principle Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K251395

Trade/Device Name: Rialto™ SI Fusion System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: OUR
Dated: March 4, 2025
Received: May 5, 2025

Dear Rong Guo:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Maziar Shah-
mohammadi -S



[For] Colin O'Neill, M.B.E.

Assistant Director

DHT6B: Division of Spinal Devices

OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K251395

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Please provide the device trade name(s).

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The Rialto™ SI Fusion System

Please provide your Indications for Use below.

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

Please select the types of uses (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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510(k) Summary
MEDTRONIC Sofamor Danek USA, Inc.
April 8, 2025

- I. Submitter** Medtronic Sofamor Danek, USA Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
Contact: Rong Guo
Principle Regulatory Affairs Specialist
Email: rong.guo@medtronic.com
Date Prepared: April 8, 2025
- II. Subject Device**
- Name of Device: Rialto™ SI Fusion System
- Classification OUR
Product Codes:
- Common name: Sacroiliac Joint Fixation
- Classification Smooth or Threaded Metallic Bone Fixation Fastener
Name:
Classification Class II
- III. Predicate** Rialto™ SI Fusion System – Implant, K161210 (SE
Devices: 08/12/2016)
- IV. 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 Screws 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

V.	<u>Indications for use</u>	<u>RIALTO™ SI Fusion System</u> The RIALTO™ SI Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.
VI.	<u>Comparison of Technological Characteristics with the Predicate Devices</u>	This 510K submission is to add MRI information to the subject devices labeling. The subject devices do not have any change of the technological characteristics from the predicate devices.
VII.	<u>Performance Data</u>	In accordance with the FDA Guidance “Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment” the subject Medtronic Anterior Cervical Plate Systems were evaluated for MR-safety in accordance with the following standards: • RF-Induced heating: ASTM F2182-19e2 • Magnetically Induced Force: ASTM F2052-21 • Magnetically Induced Torque: ASTM F2213-17 • Image Distorsion: ASTM F2119-24 • Labelling: ASTM F2503-23
VIII.	<u>Conclusion:</u>	Based on the non-clinical test results and additional supporting documentation provided in this pre-market notification, the subject devices demonstrated substantial equivalence to the listed predicate devices.