Medtronic Sofamor Danek, USA Inc.
Bhavya Vendra
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K191066
Trade/Device Name: CD Horizon™ Astute™ Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NQP
Dated: September 5, 2019
Received: September 6, 2019

Dear Bhavya Vendra:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.


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,

Colin O'neill -S

(Ronald Jean) Vacant
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
Device Name
CD Horizon™ Astute™ Spinal System

Indications for Use (Describe)
The CD Horizon™ Astute™ Spinal System is intended to provide for posterior, supplemental fixation when used with an interbody fusion cage for patients diagnosed with degenerative disc disease (DDD- defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level. This device is intended for 1-2 level use in the lumbosacral spine (L2 - S1) in skeletally mature patients. The device is intended for use with an interbody fusion cage at the instrumented level and is not intended for stand-alone use.

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)
510(k) Summary
April 2019

I. Submitter: Medtronic Sofamor Danek, USA Inc.
1800 Pyramid Place
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Contact: Bhavya Vendra
Regulatory Affairs Specialist
Telephone Number: (901) 396-3133
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II. Device:

Proprietary Trade Name: CD Horizon™ Astute™ Spinal System
Common Name: Rod, Set Screw
Classification Name: Thoracolumbosacral pedicle screw system

Regulation Numbers: 888.3070
Classification: Class II
Product Code: NQP

III. Predicates:

Primary Predicate:
CD Horizon™ Spinal System (K182928, S.E. 01/11/2019)

Additional Predicates:
Sovereign™ Spinal System (K172328, S.E. 11/02/2017)
T2 Stratosphere™ Expandable Corpectomy System (K183510, S.E. 01/16/2019)

These predicates have not been subject to a design-related recall.
IV. Product Description:
The CD Horizon™ Astute™ Spinal System consists of a variety of sizes of rods, as well as set screws, which are used with bone screws from the CD Horizon™ Solera™ Spinal System, to create a variety of rigidly locked configurations, with each construct being tailored to the individual case. The CD Horizon™ Astute™ Spinal System implant components are fabricated from medical grade titanium alloy, tantalum, or polyetheretherketone (PEEK).

V. Indications for Use:
The CD Horizon™ Astute™ Spinal System is intended to provide for posterior, supplemental fixation when used with an interbody fusion cage for patients diagnosed with degenerative disc disease (DDD- defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level. This device is intended for 1-2 level use in the lumbosacral spine (L2 – S1) in skeletally mature patients. The device is intended for use with an interbody fusion cage at the instrumented level and is not intended for stand-alone use.

VI. Comparison of Technological Characteristics:
The subject CD Horizon™ Astute™ Spinal System consists of multiple components which allows the surgeon to build an implant construct to fit the individual patient’s anatomical and physiological requirements. The spinal implant assembly consists of a combination of set screws, and rods.

The subject system has similar technological features as compared to the predicate devices:

- The subject devices share similar materials, manufacturing process, intended use, operating principle, fundamental scientific technology and indications as the predicate CD Horizon™ Spinal System.
- The subject devices share the similar design concept as the predicate CD Horizon™ Spinal System (K182928, S.E. 01/11/2019).
- The subject device shares the same sterilization process as the predicate devices.

VII. Performance Data:

Mechanical Testing:
In order to demonstrate substantial equivalence to the predicate devices, mechanical testing was performed on the subject and predicate devices in accordance with ASTM F1717, Standard test Methods for Spinal Implant Constructs in a Vertebrectomy Model and ASTM F1798, Standard Guide for
Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Sub-assemblies Used in Spinal Arthrodesis Implants.

Mechanical testing included static and dynamic compression bending and static torsion testing per ASTM F1717, and static axial grip, static torsional grip, and static and dynamic flexion/extension testing per ASTM F1798.

The subject devices met the pre-determined acceptance criteria for all tests.

**Clinical Performance:**

Data from the predicate device’s retrospective study was included to support to use of the subject CD Horizon™ Astute™ Spinal System to provide stabilization in interbody fusion procedures for the treatment of DDD. Clinical literature was also provided to support the use of the subject device construct as supplemental fixation for interbody cages for the treatment of DDD.

**VIII. Conclusion:**

Based on the supporting documentation provided in this pre-market notification, the subject devices demonstrated substantial equivalence to the legally marketed predicate devices.