



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Medtronic Sofamor Danek USA, Incorporated
Ms. Laveeda Leflore
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

November 12, 2015

Re: K152623

Trade/Device Name: ATLANTIS® Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: September 11, 2015
Received: September 14, 2015

Dear Ms. Leflore:

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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152623

K152623

Page 1 of 1

Device Name

ATLANTIS® ANTERIOR CERVICAL PLATE SYSTEM

Indications for Use (Describe)

Properly used, this system is intended for anterior interbody screw fixation from C2 to T1. The indications and contraindications of spinal instrumentation systems should be well understood by the surgeon. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with: 1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), 2) trauma (including fractures), 3) tumors, 4) deformity (defined as kyphosis, lordosis, or scoliosis), 5) pseudarthrosis, and/or 6) failed previous fusions.

NOTA BENE: This device system is intended for anterior cervical intervertebral body fusions only.

WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

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

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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

Contact: **Laveeda Leflore**
Regulatory Affairs Specialist

II. Proprietary Trade Name: **ATLANTIS® Anterior Cervical Plate System**

III. Classification Name: **Spinal Intervertebral Body Fixation Orthosis
(888.3060)**

IV. Classification: **Class II**

V. Predicate Devices **K021461 ATLANTIS® Anterior Cervical Plate
System (S.E. 07/22/2002) – Primary Predicate**
**K063100 ATLANTIS® Anterior Cervical Plate
System (S.E. 02/23/2007)**
**K130640 ATLANTIS® Anterior Cervical Plate
System (S.E. 06/04/2013)**
**K141632 ZEVO® Anterior Cervical Plate System
(S.E. 12/04/2014)**

VI. Product Codes: **KWQ**

VII. Product Description

The ATLANTIS® Anterior Cervical Plate System consists of a variety of shapes and sizes of bone plates (set screws and washers are pre-assembled to the plates), screws, and associated instruments. Fixation is provided by bone screws inserted into the vertebral body of the cervical spine using an anterior approach.

The ATLANTIS® Anterior Cervical Plate System implant components are made from titanium alloy, with certain plates having subcomponents manufactured from shape memory alloys (Nitinol-NiTi). Stainless steel and titanium implant components must not be used together in a construct. Do not use any of the ATLANTIS® Anterior

Cervical Plate System components with the components from any other system or manufacturer.

The subject devices are manufactured from ASTM F136 Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI Alloy for Surgical Implant Applications.

The subject plates and bone screws are implants that are single use only. The subject implants are provided sterile by gamma irradiation.

VIII. Indications for Use

Properly used, this system is intended for anterior interbody screw fixation from C2 to T1. The indications and contraindications of spinal instrumentation systems should be well understood by the surgeon. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with: 1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), 2) trauma (including fractures), 3) tumors, 4) deformity (defined as kyphosis, lordosis, or scoliosis), 5) pseudarthrosis, and/or 6) failed previous fusions.

NOTA BENE: This device system is intended for anterior cervical intervertebral body fusions only.

WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

VII. Summary of the Technological Characteristics

The subject devices are identical to the predicate in terms of intended use, overall dimensions, and fundamental scientific technology as the previously cleared predicates. Like the predicates, the subject plates and bone screws are available in titanium alloy. Also like the predicates, the plates are offered in sizes ranging from 19mm- 110mm, and the bone screws are offered in sizes 4.0mm and 4.5mm in diameter and 10-20mm in length. The subject plates and bone screws will be provided sterile.

VIII. Identification of Legally Marketed Devices

The design features and indications for use for the sterile subject devices are substantially equivalent to the predicate ATLANTIS® Anterior Cervical Plate System (K021461, S.E. 07/22/2002; K063100 S.E. 02/23/2007; K130640 S.E. 06/04/2013) and ZEVO® Anterior Cervical Plate System (K141632 S.E. 12/04/2014).

IX. Discussion of Non-Clinical Testing:

Sterilization assessments were completed for the sterile subject plates and screws. These reports provide adequate evidence for the validated sterilization parameters. The shelf life rationale indicates that the sterile subject device package integrity has an eight year shelf life. Mechanical testing, in accordance with ASTM F1717, was also completed to support the subject device's substantial equivalence to the predicate devices. The test methods included compression fatigue, static compression, and static torsion. Compression fatigue, static torsion, and static compression testing were completed, and the test results determined the subject devices to be substantially equivalent to the predicate devices. A summary of the testing performed along with the complete test report is provided in the Bench Testing section of this submission.

X. Conclusion

Based on the non-clinical test results and additional supporting documentation provided in this pre-market notification, Medtronic believes that the subject devices demonstrated substantial equivalence to the listed predicate devices.