K121191

JUN 29 2012

510(k) Summary

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

Submitter Information	
Name	Medtronic Sofamor Danek USA, Inc.
Address	1800 Pyramid Place Memphis, TN 38132
Phone number	901-344-0804 / 901-344-1463
Fax number	901-346-9738
Establishment Registration Number	1030489
Name of contact person	Claire Evans / Nicholas Tabrizi
Date prepared	April 18, 2012
Name of device	
Trade or proprietary name	VERTEX® Reconstruction System
Common or Usual name	Metallic Orthopedic Plate, Rod and Screw
Classification name	Spinal Interlaminal Fixation Orthosis, Single/Multiple Component Metallic Bone Fixation Appliances and Accessories, Pedicle Screw System
Classification	Class II
Regulation	888.3050
Product Code(s)	KWP
Legally marketed device(s) to which equivalence is claimed	See table below
Reason for 510(k) submission	The purpose of this 510(k) is to modify the connectors and add a 5.5mm multi-axial screw to the VERTEX® SELECT Reconstruction System. Two changes are being proposed to the connectors: (1) The thread depth and drill depth of the set screw threaded hole on the connector is increasing and (2) the tolerance on the rod slot diameter will be widened.

510(k) Number	Title	Date Cleared
K090714	VERTEX® Reconstruction System, VERTEX SELECT® Reconstruction System	4/17/09
K082728	VERTEX® Reconstruction System, VERTEX SELECT® Reconstruction System	1/16/09
K083071	VERTEX® Reconstruction System	11/14/08
K042789	VERTEX® Reconstruction System	12/21/04

Device description	The VERTEX SELECT® Reconstruction System is a posterior system, which consists of a variety of shapes and sizes of plates, rods, hooks, screws, multi-axial screws, and connecting components, which can be rigidly locked to the rod in a variety of configurations, with each construct being tailor-made for the individual case. Titanium ATLAS® cable may be used with this system at the surgeon's discretion. See the package inserts of both of those systems for labeling limitations. The VERTEX® Reconstruction System is fabricated from medical grade titanium, medical grade titanium alloy, and medical grade cobalt chromium. Medical grade titanium, medical grade titanium alloy, and/or medical grade cobalt chromium may be used together. Never use titanium, titanium alloy, and/or cobalt chromium with stainless steel in the same construct. The VERTEX® Reconstruction System includes a retaining ring for the multi-axial screw made of Shape Memory Alloy (Nitinol – NiTi). Shape Memory Alloy is compatible with titanium, titanium alloy, and cobalt chromium implants only. Some components contain elastomeric stakes made of silicone adhesive commonly used in implantable medical devices. Do not use with stainless steel. To achieve best results, do not use any of the VERTEX® Reconstruction System implant components with components from any other system or manufacturer unless specifically labeled to do so in this or another MEDTRONIC document. As with all orthopaedic and neurosurgical implants, none of the VERTEX® Reconstruction System components should ever be reused under any circumstances.
Intended use of the device	When intended to promote fusion of the occipitocervical spine, cervical spine, and the thoracic spine, (Occiput-T3), the VERTEX® Reconstruction System is indicated for the following: DDD (neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, failed previous fusion and/or tumors.
Indications for use	When intended as an adjunct to fusion of the occipitocervical spine, cervical spine, and the thoracic spine (Occiput-T3), the VERTEX® Reconstruction System is indicated for skeletally mature patients using allograft and/or autograft for the following: DDD (neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, failed previous fusion, and/or tumors. ***Occipitocervical Components: Plate Rod/Plates/Rods/Occipital Screws/Hooks*** The occipitocervical plate rods, plates, rods, occipital screws, and hooks are intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the occipitocervical junction and the cervical spine. When used to treat these occipitocervical and cervical conditions, these screws are limited to occipital fixation only. The screws are not intended to be placed in the cervical spine. Occipitocervical constructs require bilateral fixation to C2 and below. **Note:** Segmental fixation is recommended for these constructs.

	Hooks and Rods The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine. ***Multi-axial Screws*** The use of multi-axial screws is limited to placement in T1-T3. The screws are not intended to be placed in the cervical spine. Titanium ATLAS® Cable System to be used with the VERTEX® Reconstruction System allows for cable attachment to the posterior cervical or thoracic spine. ***Connectors*** In order to achieve additional levels of fixation, the VERTEX® Reconstruction System may be connected to the CD HORIZON® Spinal System rods with the VERTEX® rod connectors. Transition rods with differing diameters may also be used to connect the VERTEX® Reconstruction System to the CD HORIZON® Spinal System screws, hooks, and connectors. Refer to the CD HORIZON® Spinal System package insert for a list of the CD HORIZON® Spinal System indications of use.
Summary of the technological characteristics of the device compared to the predicate device	The primary change from the predicate devices for the connectors is the minimum thread depth and maximum drill depths are increased on the subject device. In relation with the depth changes, the tolerance on the wide slot diameter was widened to accommodate the increase in thread depth and drill depth. The primary change from the predicate devices for the multi-axial screw is the diameter is being increased from 4.5mm to 5.5mm on the subject device.

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Performance Test Summary-New Device

Characteristic	Standard/Test/FDA Guidance	Results Summary
N/A	N/A	N/A

Comparative Performance Information Summary

Characteristic	Requirement	New Device	Predicate Device
N/A	N/A	N/A	N/A

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION

Not Applicable

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA
The changes proposed to the connectors: 1)increasing thread and drill depth of the set screw hole on the connector and 2) widening the tolerance on the rod slot diameter, as well as the changes to the multi-axial screw, do not require additional bench testing since neither presents a new worse case scenario. Therefore, the subject VERTEX® Reconstruction System connectors and multi-axial screw are safe and effective and perform as well as the predicate VERTEX ® Reconstruction System connectors and multi-axial screw.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

JUN 29 2012

Medtronic Sofamor Danek USA, Inc.
% Ms. Claire Evans
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K121191
Trade/Device Name: Vertex® Reconstruction System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP
Dated: April 18, 2012
Received: April 19, 2012

Dear Ms. Evans:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K121191

Device Name: VERTEX® Reconstruction System

Indications for Use:

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Occipitocervical Components: Plate Rod/Plates/Rods/Occipital Screws/Hooks
The occipitocervical plate rods, plates, rods, occipital screws, and hooks are intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the occipitocervical junction and the cervical spine. When used to treat these occipitocervical and cervical conditions, these screws are limited to occipital fixation only. The screws are not intended to be placed in the cervical spine.

Occipitocervical constructs require bilateral fixation to C2 and below.
Note: Segmental fixation is recommended for these constructs.

Hooks and Rods
The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

Multi-axial Screws
The use of multi-axial screws is limited to placement in T1-T3. The screws are not intended to be placed in the cervical spine.
Titanium ATLAS® Cable System to be used with the VERTEX® Reconstruction System allows for cable attachment to the posterior cervical or thoracic spine.

Connectors
In order to achieve additional levels of fixation, the VERTEX® Reconstruction System may be connected to the CD HORIZON® Spinal System rods with the VERTEX® rod connectors. Transition rods with differing diameters may also be used to connect the VERTEX® Reconstruction System to the CD HORIZON® Spinal System screws, hooks, and connectors. Refer to the CD HORIZON® Spinal System package insert for a list of the CD HORIZON® Spinal System indications of use.

Prescription Use ____X__ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K121191