

**VERTEX® Reconstruction System
510(k) Summary**

DEC 18 2012

November 2012

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

Contact: Michael Scott
Senior Regulatory Affairs Specialist

II. **Proprietary Trade Name:** VERTEX® Reconstruction System

III. **Classification Name:**

Regulation Name: Spinal Interlaminar Fixation Orthosis
Class: II
Product Codes: KWP
Regulation Number: 21 CFR 888.3050

IV. **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.

The purpose of this Special 510(k) is to add additional components to the VERTEX® Reconstruction System: namely a fixed length and lower profile CROSSLINK® Connector to allow the surgeon additional construct rigidity options when using the VERTEX® Reconstruction System rods and connector components.

V. 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.

VI. Summary of the Technological Characteristics:

The purpose of this 510(k) is to add additional components to the VERTEX® Reconstruction System. The subject and predicate parts are identical in terms of material, indications for use, intended use, and performance specifications. The key difference between the subject and primary predicate device is the modification from variable length connectors to fixed length connectors.

VII. Identification of Legally Marketed Devices:

The design features, materials used, manufacturing and sterilization methods and indications for use of the subject devices are equivalent to the predicate VERTEX® Reconstruction System devices (K082728 – SE 01/16/2009 and K023555 – SE 11/22/2002). The labeling is identical to that cleared in K121191 (S.E. 06/29/12).

VIII. Discussion of the Non-Clinical Testing:

Medtronic provided an engineering rationale and a risk assessment which demonstrate that the subject VERTEX® Reconstruction System CROSSLINK® does not introduce new issues of safety or effectiveness.

IX. Conclusions:

A risk analysis was completed for the changes incorporated into the subject devices. Based on the results and additional supporting documentation provided in this submission, the subject devices demonstrated substantial equivalence to the previously listed predicate devices.



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

Medtronic Sofamor Danek USA, Incorporated
% Mr. Michael Scott
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Letter dated: December 18, 2012

Re: K123568

Trade/Device Name: VERTEX® Reconstruction System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminar fixation orthosis
Regulatory Class: Class II
Product Code: KWP
Dated: November 19, 2012
Received: November 20, 2012

Dear Mr. Scott:

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

Page 2 – Mr. Michael Scott

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

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

Enclosure

510(k) Number (if known): K123568

Device Name: VERTEX® Reconstruction System

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.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)

Division of Orthopedic Devices

510(k) Number: K123568