MEDTRONIC Sofamor Danek
MSB Sacroiliac Joint Fusion Device
510(k) Summary - K110472
May 2012

MAY 29 2012

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

Contact: Lee Grant
Senior Principal, Regulatory Affairs

Product Name: MSB Sacroiliac Joint Fusion Device
Regulation Name: Smooth or Threaded Metallic Bone Fastener
Classification: 21 CFR 888.3040 – Product Code: OUR

Description: The MSB Sacroiliac Joint Fusion Device is designed to provide stabilization of the sacroiliac joint until fusion occurs. This product is manufactured from medical grade titanium alloy (Ti-6AL-4V) conforming to ASTM F136. The device is offered in a variety of sizes ranging from 5mm to 12mm in diameter and from 20mm to 60mm in length. One design option consists of a solid outer form. The alternative design contains holes along the sides of the implants which can be used to pack graft material. Both versions are cannulated and may be implanted via a minimally invasive approach.

Indications for Use: The MSB Sacroiliac Joint Fusion Device is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroillitis.

Non-Clinical Performance Data: Engineering calculations were provided to demonstrate that under worst-case conditions the subject devices will not raise any new issues of safety or effectiveness. Engineering analysis of the MSB device measured against the SI-Bone device and test items similar to the Pioneer Cannulated Screw found that the devices were substantially equivalent. Additionally, push out, torque-to-fail and four-point bending testing was also performed in accordance with ASTM F543-07, Standard Specification and Test Methods for Metallic Medical

Bone Screws and ASTM F2193-02, Standard Specification and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System.

Technological Comparison:

The MSB Sacroiliac Joint Fusion Device technological characteristics do not raise any new questions of safety or effectiveness.

Substantial Equivalence:

Documentation was provided which demonstrated that the subject device is substantially equivalent to the iFuse Implant System manufactured by SI-Bone (K110838, SE 04/21/11, K092375, SE 09/04/09 and K080398, SE 11/26/08); as well as the Pioneer Cannulated Screw System (K102903, SE 10/20/10); Globus Medical SI-LOK Sacroiliac Joint Fixation System (K112028, SE 12/09/11); Zyga's Simmetry™ Sacroiliac Joint Fusion System (K111801, 7/21/11), the DePuy SIJF Cannulated Screw System (K051296, SE 08/26/05), the Synthes 6.5 Cannulated Screw (K021932, SE 09/06/02) and the Alphatec Cannulated Bone Screws (K914004, SE 12/05/91).

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

MAY 29 2012

Medtronic Sofamor Danek, Inc.
% Mr. Lee Grant
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K110472
Trade/Device Name: MSB Sacroiliac Joint Fusion Device
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: OUR
Dated: May 22, 2012
Received: May 23, 2012

Dear Mr. Grant:

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,

for 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): K110472

Device Name: MSB Sacroiliac Joint Fusion Device

Indications for Use: The MSB Sacroiliac Joint Fusion Device is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroillitis.

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 K110472