CRESCENT® Spinal System Titanium
510(k) Summary
July 2011

AUG - 9 2011

I. COMPANY:

Medtronic Sofamor Danek USA
1800 Pyramid Place
Memphis, Tennessee 38132

II. CONTACT:

Becky Ronner
Regulatory Affairs Specialist
Telephone: (901) 399-2757
Fax: (901) 346-9738

III. PROPOSED PROPRIETARY TRADE NAME:

CRESCENT® Spinal System Titanium

IV. CLASSIFICATION NAMES:

Intervertebral Body Fusion Device

CLASS:

II

PRODUCT CODE:

MAX (21 CFR 888.3080)

V. PRODUCT DESCRIPTION:

The CRESCENT® Spinal System Titanium is intended to help provide support in the intervertebral body space during fusion of vertebral bodies in the lumbar spine. This system is intended to be used with supplemental fixation.

The CRESCENT® Spinal System Titanium consists of a variety of hollow intervertebral body spacers featuring a bullet nosed, anatomically shaped design with axial voids designed to hold bone graft material. The subject devices are designed with diamond V teeth across both superior and inferior surfaces to allow the implant to grip the superior and inferior end plates, thus allowing expulsion resistance. The subject devices are manufactured from anodized medical grade titanium alloy (Ti-6Al-4V).

The purpose of this submission is to add CRESCENT® Spinal System Titanium intervertebral body fusion devices to the CRESCENT® Spinal System family.

VI. INDICATIONS FOR USE:

The CRESCENT® Spinal System Titanium is indicated for interbody fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined

as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants are to be used with autogenous bone graft. These devices are intended to be used with Medtronic supplemental fixation instrumentation which has been cleared by the FDA for use in the lumbar spine.

VII. Summary of the Technological Characteristics:

The purpose of this Special 510(k) submission is to include Titanium Alloy Intervertebral body Fusion Device into the CRESCENT® Spinal System family. The current CRESCENT® Spinal System is offered in polyetheretherketone (PEEK) material. The design is essentially the same fundamental technology with minor dimensional changes.

VIII. Identification of Legally Marketed Devices:

The design features and indications for use for the subject CRESCENT® Spinal System Titanium are substantially equivalent to the following predicates:

- CRESCENT® Spinal System K094025
- LT-CAGE® Titanium Lumbar Tapered Fusion Device P9710015/S010
- CLYDESDALE® Spinal System K100175
- CAPSTONE® Spinal System K073291

IX. Discussion of Non-Clinical Testing:

The subject Intervertebral Body Fusion Devices were tested using Finite Element Analysis (FEA) and confirmatory supplemental testing in accordance with ASTM F2077 and ASTM F2267. This testing was compared to previously listed predicate devices. The subject devices met the predetermined acceptance criteria for all tests. Tests results were provided to demonstrate that the subject devices are substantially equivalent to the predicate devices.

X. Conclusion:

A risk analysis was completed, non-clinical validated FEA simulated testing was performed and confirmatory supplemental testing in accordance with ASTM F2077 and ASTM F2267. Based on the test results and additional supporting documentation provided in this premarket notification, the subject devices demonstrated substantial equivalence to listed predicate devices.

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

Medtronic Sofamor Danek USA
% Ms. Becky Ronner
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

AUG - 9 2011

Re: K110543
Trade/Device Name: Crescent Spinal System Titanium
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: July 05, 2011
Received: July 11, 2011

Dear Ms. Ronner:

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): K110543

Device Name: CRESCENT® Spinal System Titanium

Indications for Use:

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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 K110543