K092087

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Medtronic Sofamor Danek
Medtronic Dental TCP
510(k) Summary
July 2009

DEC 30 2009

I. **Company:** **Medtronic Sofamor Danek USA, Inc.**
1800 Pyramid Place
Memphis, TN 38132
Telephone: (901) 396-3133
Fax: (901) 346-9738

Contact: **Pamela Edwards**
Regulatory Affairs Specialist

II. **Proposed Proprietary Trade Name:** Medtronic Dental TCP
Classification Name: Filler, bone void, calcium compound
Product Code: LYC
Regulation No.: 872.3930

III. **Product Description/Purpose of Application**

Medtronic Dental TCP is a porous, resorbable, osteoconductive bone grafting material made of medical grade β-tricalcium phosphate. Medtronic Dental TCP is supplied sterile for single patient use. The device is an osteoconductive, porous implant that allows for bony ingrowth across the graft site while resorbing at a rate consistent with bone healing. The product is biocompatible.

The purpose of this 510(k) application is to seek marketing clearance for Medtronic Dental TCP for use as a synthetic, resorbable bone void filler in the oral and maxillofacial region. Like the previously cleared predicates, MASTERGRAFT® Resorbable Ceramic Granules (K082917, SE 01/09/09), Synthes (USA) chronOS™- β-TCP (K053022, SE 01/23/06) and Cerasorb® Dental (K051443, SE 07/22/05), the subject system is intended as a bone void filler for bony voids or gaps that are not intrinsic to the stability of the bony structure. In addition, Medtronic Dental TCP can be mixed with autograft and used as a bone graft extender.

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IV. Indications

Medtronic Dental TCP is indicated as a bone void filler in bony voids or gaps, not intrinsic to the stability of the bony structure of the oral and maxillofacial region. The voids or gaps may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Medtronic Dental TCP provides a bone void filler that is resorbed/remodeled and is replaced by host bone during the healing process.

Medtronic Dental TCP is intended for the augmentation of deficient maxillary and mandibular alveolar ridges and the treatment of oralmaxillofacial and dental intraosseous defects. Procedures include:

- Ridge augmentation
- Sinus augmentation
- Filling of cystic defects
- Filling of extraction sites
- Filling of lesions of periodontal origin
- Craniofacial augmentation
- Filling of defects of endodontic origin
- Mandibular reconstruction
- Repair of traumatic defects of the alveolar ridge, excluding maxillary and mandibular fracture
- Filling of resection defects in benign bone tumors, benign cysts or other osseous defects in the alveolar ridge wall

Medtronic Dental TCP may be used alone, or in combination with saline, blood, bone marrow aspirate or platelet rich plasma (PRP).
Medtronic Dental TCP may be mixed with autograft as a bone graft extender.

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V. Substantial Equivalence

Documentation provided in this submission demonstrates that the subject device is substantially equivalent to the previously cleared devices including MASTERGRAFT® Resorbable Ceramic Granules (K082917, SE 01/09/09), Synthes (USA) chronOS™- β-TCP (K053022, SE 01/23/06) and Cerasorb® Dental (K051443, SE 07/22/05).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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

DEC 30 2009

Re: K092087
Trade/Device Name: Medtronic Dental TCP
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: December 22, 2009
Received: December 23, 2009

Dear Ms. Edwards:

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.

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

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K092087

510(k) Number (if known):

Device Name: Medtronic Dental TCP

Indications for Use:

Medtronic Dental TCP is indicated as a bone void filler in bony voids or gaps, not intrinsic to the stability of the bony structure of the oral and maxillofacial region. The voids or gaps may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Dental TCP provides a bone void filler that is resorbed/remodeled and is replaced by host bone during the healing process.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X___ OR Over-The-Counter Use _____
Per 21 CFR 801.109

ASBetz DDS for Dr. K. P. Mulay (Acting)
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092087