

**CAPSTONE® Spinal System
510(k) Summary – K073291
April 2008**

APR 24 2008

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

**Contact: Lee Grant
Senior Project Specialist, Regulatory Affairs**

II. Proprietary Trade Name: CAPSTONE® Spinal System

III. Classification Name: Intervertebral Body Fusion Device (21 CFR 888.3080)

IV. Product Code: MAX

V. Product Description

The CAPSTONE® PEEK Spinal System consists of a variety of hollow vertebral body spacers featuring a convex, bullet nose design and an axial void designed to hold bone graft material. The subject device is made of various lengths. The subject devices are designed with angular teeth to allow the implant to grip the superior and inferior end plates, thus allowing expulsion resistance. The devices range from 6mm to 16mm in height and from 22mm to 36mm in length.

V. Indications

The CAPSTONE® Spinal System is indicated for use 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 I 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 may be implanted via an open or a minimally invasive posterior approach. Alternatively, these implants may also be implanted via an anterior and/or transforaminal approach. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.

VI. Substantial Equivalence

Documentation, including mechanical test results and published literature, was provided which demonstrated that the subject CAPSTONE® Spinal System is substantially equivalent to five recently down classified interbody cages, the LT-CAGE® Peek Lumbar Tapered Fusion Device (P970015, Medtronic Sofamor Danek, Approved 9/10/03), the BAK® Cage (P950002, Zimmer Spine, Approved 7/8/03), the RAY® Threaded Fusion Cage (P950019, Stryker, Approved 9/4/03), the Lumbar I/F Cage (P960025, DePuy, Approved 3/4/05) and the PARAMOUNT INTERVERTEBRAL BODY FUSION Device (K072120, Innovative Spinal Technologies, SE 10/11/07).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

APR 24 2008

Re: K073291
Trade/Device Name: CAPSTONE® Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX
Dated: April 11, 2008
Received: April 14, 2008

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K073291

Device Name: CAPSTONE® Spinal System

Indications for Use:

The CAPSTONE® Spinal System is indicated for use 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 may be implanted via an open or a minimally invasive posterior approach. Alternatively, these implants may also be implanted via an anterior and/or transforaminal approach. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(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)

Neil R. P. Doyle
(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K073291