K071375

510(K) Summary

Disc-O-Tech Medical Technologies Ltd.

Confidence Bone Cement Delivery System - Mesh Introducer Needle

Submitter Name

Disc-O-Tech Medical Technologies Ltd.
11 Ha'Hoshlim St.,
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Contact Person

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Disc-O-Tech Medical Technologies Ltd.
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DEC 2 1 2007

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Date Prepared

May 2007

Trade/Proprietary Name

Mesh Fenestrated Introducer Needle (Mesh Introducer Needle)

Common Name

Needle

Classification Name

Orthopedic Manual Surgical Instrument

Predicate Devices

- ✓ Confidence High Viscosity Bone Cements (K060300, K062424)
- ✓ Confidence Fenestrated Introducer Needle (K063067)
- ✓ Super Revo® Herculine™ Suture Anchor, by Linvatec Corporation (K041713) (and Force Fiber™ Polyethylene Nonabsorbable Surgical Suture, by TeleFlex Medical (K033654)).

Intended Use

The Mesh Introducer Needle is indicated for use in combination with the Confidence Bone Cement Delivery System. The Confidence Bone Cement Delivery System is intended for percutaneous delivery of Confidence Bone Cements, which are indicated for fixation of pathological fractures of the vertebral body during vertebroplasty or kyphoplasty procedures.

System Description

The Mesh Introducer Needle is a combination of a Bone Access Assembly (Single Step Instrument) and a Mesh Assembly. The Bone Access Assembly comprises a cannula (acting as a working channel), a dilator-reamer, and a K-wire. The Mesh Assembly comprises a fabric-made mesh (pouch) through which the bone cement is introduced into the treatment site, mounted on a small diameter injection cannula, provided with a blunt edge stylet.

Substantial Equivalence

In general, the Mesh Introducer Needle intended use, design, materials, technological characteristics, and principles of operation are substantially equivalent to those of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 1 2007

Disc-O-Tech Medical Technologies, Ltd.
% Mr. Yael Rubin
11 Ha'Hoshlim Street
Herzliya 46724, Israel

Re: K071375
Trade/Device Name: Mesh Fenestrated Introducer Needle (Mesh Introducer Needle)
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: NDN, OAR
Dated: September 20, 2007
Received: September 25, 2007

Dear Mr. Rubin:

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.

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

Indication for Use

510(K) Number (if known): _____

Device Name: Mesh Fenestrated Introducer Needle (Mesh Introducer Needle)

Indication for Use:

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Prescription Use ____√____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buehler

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071375