K063067 p 1/2

510(K) Summary

NOV - 3 2006

Disc-O-Tech Medical Technologies Ltd.

Confidence Bone Cement Delivery System - Fenestrated Introducer Needle

Submitter Name

Disc-O-Tech Medical Technologies Ltd.
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Herzliya 46724, Israel

Contact Person

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Tel: 202 637 5794, Fax: 202 637 5910

Date Prepared

October 2006

Trade/Proprietary Name

Confidence Fenestrated Introducer Needle

Common Name

Needle

Classification Name

Orthopedic Manual Surgical Instrument

Predicate Devices

✓ Confidence High Viscosity Bone Cements (K060300, K062424)

Intended Use

The Confidence Bone Cement Delivery System is intended for percutaneous delivery of bone cement, during vertebroplasty/kyphoplasty procedures

System Description

The Confidence Fenestrated Introducer Needle, a part of the Confidence Cement Delivery System, is combined of a cannula and a stylet. The cannula has a diamond-shape closed distal tip, and has numerous holes located around its distal section.

Substantial Equivalence

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Disco-O-Tech Medical Technologies, Ltd.
% Hogan & Hartson, L.L.P
Mr. Jonathan S. Kahan, Esq.
555 Thirteenth Street, Northwest
Washington, District of Columbia 20004

NOV - 3 2006

Re: K063067
Trade/Device Name: Confidence Cement Delivery System
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: NDN
Dated: October 4, 2006
Received: October 6, 2006

Dear Mr. Kahan:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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): K063067

Device Name: Confidence Cement Delivery System

Indication for Use:

The Confidence Cement Delivery System is intended for percutaneous delivery of Confidence bone cement, which is indicated for fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancer, myeloma).

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)

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

510(k) Number K063067