K062424

510(K) SUMMARY

SEP 14 2006

Disc-O-Tech Medical Technologies Ltd.

Confidence EX High Viscosity Bone Cement

Submitter Name

Disc-O-Tech Medical Technologies Ltd.

11 Ha'Hoshlim St.,

Herzeliya 46724, Israel

Contact Person

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Date Prepared

August 2006

Trade/Proprietary Name

Confidence EX High Viscosity Bone Cement

Common Name

PMMA Bone Cement

Classification Name

Filler, Bone Cement (For Vertebroplasty)

Classification

Class II, per 21 CFR §888.3027

Predicate Devices

Disc-O-Tech's Confidence High Viscosity Bone Cement (K060300)

Intended Use

The Disc-O-Tech Confidence EX High Viscosity Bone Cement is indicated for the 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).

System Description

The Confidence EX High Viscosity Bone Cement is a radiopaque, self-curing, high viscosity PMMA bone cement. It is provided sterile, as a two-component system (22.5 g powder (polymer) and 9.2 g liquid (monomer)), which are mixed prior to use to form the cement. The powder component contains 30.07 % barium sulfate.

Substantial Equivalence

Based on the information provided in this premarket notification, the Confidence EX High Viscosity Bone Cement intended use, chemical composition, material properties, biocompatibility, technological characteristics, performance, principles of operation, and clinical application are substantially equivalent to those of the predicate devices, and especially to those of the Confidence High Viscosity Bone Cement.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 4 2006

Disc-O-Tech Medical Technologies, Ltd.
% Jonathan S. Kahan, Esq.
Hogan and Hartson, LLP
555 Thirteenth Street, NW
Washington, DC 20004

Re: K062424
Trade/Device Name: Confidence EX High Viscosity Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: NDN
Dated: August 14, 2006
Received: August 18, 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) 276-0120 . 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
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: Confidence EX High Viscosity Bone Cement

Indication for Use:

The Disc-O-Tech Confidence EX High Viscosity Bone Cement is indicated for the 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)

Barbara Buchman

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

510(k) Number K062424