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K060300
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510(K) Summary

Disc-O-Tech Medical Technologies Ltd. *
Confidence High Viscosity Bone Cement

Applicant Name

Disc-O-Tech Medical Technologies Ltd.
11 Ha'Hoshlim St.,
Herzeliya 46724, Israel

Contact Person

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Disc-O-Tech Medical Technologies Ltd.
11 Ha'Hoshlim St., Herzeliya 46724, Israel
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2. Jonathan S. Kahan, Esq.
Hogan & Hartson L.L.P
555 Thirteenth Street, NW, Washington, DC 20004
Tel: 202-637-5794, Fax: 202-637-5910

Date Prepared

January 2006

Trade/Proprietary Name

Confidence High Viscosity Bone Cement

Common Name

PMMA Bone Cement

Disc-O-Tech Medical Technologies Ltd.
Confidence High Viscosity Bone Cement 510(k)

Classification Name

Filler, Bone Cement (For Vertebroplasty)

Classification

Class II, per 21 CFR §888.3027

Predicate Devices

- ✓ Kyphon Inc.'s KyphX[®] HV-R[™] Bone Cement (K041584)
- ✓ Stryker Corp.'s Spineplex[™] Radiopaque Bone Cement (K032945)
- ✓ Cook Inc.'s Vertefix[™] Radiopaque Bone Cement (K042691)

Intended Use

The Disc-O-Tech Confidence 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 High Viscosity Bone Cement is a radiopaque, self-curing, high viscosity PMMA bone cement. It is provided sterile, as a two-component system (20 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 High Viscosity Bone Cement intended use, chemical composition, material properties, biocompatibility, principles of operation, technological characteristics, performance, and clinical application are substantially equivalent to those of the predicate devices.



JUN 21 2006

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Disc-O-Tech Medical Technologies, Inc.
c/o Jonathan S. Kahan, Esq.
Hogan & Hartson, L.L.P.
555 Thirteenth Street, NW
Washington, DC 20004-1109

Re: K060300

Trade/Device Name: Confidence High Viscosity Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: PMMA Bone Cement
Regulatory Class: II
Product Code: NDN
Dated: May 19, 2006
Received: May 19, 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.

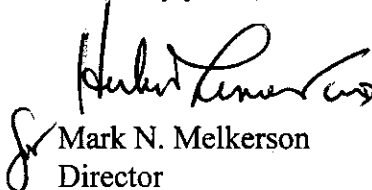
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

Page 2 – Mr. Jonathan S. Kahan, Esq.

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" (21 CFR 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,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is written in a cursive style with a large initial "M".

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): K060300

Device Name: Confidence High Viscosity Bone Cement

Indication for Use:

The Disc-O-Tech Confidence 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).

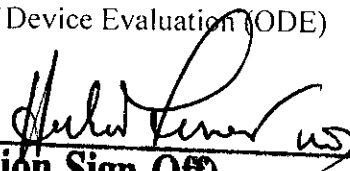
Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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 K060300