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K021788
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# 510(k) Summary of Safety and Effectiveness

In Accordance with SMDA of 1990

NBD Cement Restrictor

May 15, 2002

**Company:**
NBD, LLC
605 Industrial Court
Woodstock, GA 30189

**Trade Name:**
NBD Cement Restrictor

**Common Name:**
Cement Restrictor

**Product Code and Regulatory Classification:**
JDK: 878.3300 Surgical Mesh

**Product Classification:**
Class II

**Intended Use:**
The NBD Cement Restrictor Device is intended for use as a cement restrictor in orthopedic surgeries such as those involving the femoral canal and tibial plateau in hip stem and total knee replacement. This device is not appropriate for acetabular cup surgeries.

## Device Description:

The NBD Cement Restrictor Device is a hollow, titanium, rounded rectangular frame with fenestrated surfaces on all sides and 1mm toothed spikes on opposite sides. The device is intended to be used in conjunction with standard PMMA cement.

## Performance Data:

No applicable performance standards have been promulgated under Section 514 of the Food, Drug, and Cosmetic Act for this device. However, the material is subjected to ISO 5832-3 Implants for surgery - Wrought titanium 6-aluminum 4 vanadium alloy 1996-07-01.

## Functional & Safety Testing:

Functional and saftey testing of the NBD Cement Restrictor Device consisted of examination of the function of the device under conditions similar to those found in normal usage and testing to ensure conformance to product specifications. The results were successful and did not raise any issues of safety and effectiveness of the device.

## Substantial Equivalence:

The NBD Cement Restrictor Device is substantially equivalent to RA-BEA™ Cement Restrictor Device which was cleared for premarket notification K990345 on July 30, 1999. The NBD Cement Restrictor is equivalent in design, function, material, and indications for use.

Osteonics PTII Cement Spacer, K914406
Motech Surgical Mesh, K900138

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 4 2002

Mr. Tim B. Lusby
President
New Business Development, LLC
605 Industrial Court
Woodstock, GA 30189

Re: K021788
Trade/Device Name: NBD Titanium Cement Restrictor
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: JDK
Dated: August 13, 2002
Received: August 15, 2002

Dear Mr. Lusby:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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 (PMA) application. You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's package insert and also as a Warning on the product label:

WARNING: THIS DEVICE IS NOT INTENDED FOR ANY SPINAL INDICATIONS.

THE SAFETY AND EFFECTIVENESS OF THIS DEVICE WHEN IMPLANTED IN THE SPINE HAVE NOT BEEN ESTABLISHED.

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.

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

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

Daniel Schultz, M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number: K021788

Device Name: NBD Cement Restrictor

Indications For Use:

The NBD Cement Restrictor Device is intended for use as a cement restrictor in orthopedic surgeries such as those involving the femoral canal and tibial plateau in hip stem and total knee replacement.

The NBD Cement Restrictor is NOT intended for any spinal indications.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Millerson

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

510(k) Number K021788

(Optional Format 3-10-98)