K020836

JUN 11 2002

510(k) Summary for the RABEA Cement Restrictor Device

Submitter:

SIGNUS Medical LLC
7140 Derby Drive
Chanhassen, MN 55317

Contact Person:

Mr. Thomas Hoghaug
SIGNUS Medical LLC
7140 Derby Drive
Chanhassen, MN 55317

Date Prepared:

June 3, 2002

Trade Name:

RABEA™ Cement Restrictor

Classification Name: and Number:

Cement Restrictor
Class II, 21 CFR 878.3300

Product Code:

JDK

Predicate Device(s):

The RABEA™ Cement Restrictor is substantially equivalent to:

- RABEA™ Titanium Cement Restrictor (K990345)
- Medtronic Sofamor Danek Cement Restrictor (K013663)

Device Description:

The RABEA™ Cement Restrictor is a hollow, PEEK 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.

Intended Use:

The RABEA™ Device is intended to be used 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, nor is it intended for any spinal indications.

Functional and Safety Testing:

Functional and safety testing of the RABEA™ 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 of the examination and testing were successful and did not raise any issues of safety and effectiveness of the device.

Conclusion:

The RABEA™ Cement Restrictor Device is substantially equivalent to the RABEA™ Titanium Cement Restrictor (K990345) and the Medtronic Sofamor Danek Cement Restrictor (K013663) based upon the devices' similarities in functional design and indications for use.

K020836

page 2 of 2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 2002

Mr. Thomas Hoghaug
Managing Director
SIGNUS Medical LLC
7140 Derby Drive
Chanhassen, Minnesota 55317

Re: K020836
RABEA™ Cement Restrictor
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: JDK
Dated: March 12, 2002
Received: March 14, 2002

Dear Mr. Hoghaug:

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,

Bernard E. Statland, M.D., Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K020836 page 1 of 1

Indications for Use Page

Device Name: RABEA™ Cement Restrictor

Indications for Use: The RABEA™ Cement Restrictor is intended to be used 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, nor is it intended for any spinal indications.

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

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

510(k) Number K020836