JUL 30 1999

K990345

Attachment 2
510(k) Summary

510(K) SUMMARY

SUBMITTER:	SIGNUS Medizintechnik GmbH Rannenbergring 54 D-63755 Alzenau Germany
CONTACT PERSON:	Mr. Thomas Hoghaug Newport Medical International 27660 Woodside Road Shorewood, MN 55331 Phone: 612-470-9545 Fax: 612-470-6985
DATE PREPARED:	April 30, 1999
TRADE NAME:	RABEA™ Cement Restrictor Device
CLASSIFICATION NAME and NUMBER: **PRODUCT CODE:**	Surgical Mesh Class II, 21 CFR 878.3300 JDK
PREDICATE DEVICE(S):	The RABEA™ Cement Restrictor Device is substantially equivalent to the Osteonics PTII Cement Spacer which was cleared via premarket notification K914406 on December 20, 1991, and the Motech Surgical Mesh which was cleared for use as a cement restrictor via premarket notification K900138 on March 20, 1990.
DEVICE DESCRIPTION:	The RABEA™ Cement Restrictor Device is a hollow, titanium, rounded rectangular frame with fenestrated surfaces on all sides and 1 mm toothed spikes on opposite sides. The device is intended to be used in conjunction with standard PMMA cement.
INTENDED USE:	The RABEA™ 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.
FUNCTIONAL & 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 Osteonics PTII Cement Spacer which was cleared via premarket notification K914406 on December 20, 1991, and the Motech Surgical Mesh which was cleared for use as a cement restrictor via premarket notification K900138 on March 20, 1990, based upon the devices' similarities in functional design, materials and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 1 2001

Mr. Thomas Hoghaug
Newport Medical International
27660 Woodside Road
Shorewood, Minnesota 55331

Re: K990345
Trade Name: RABEA™ Cement Restrictor
Regulation Number: 878.3350
Regulatory Class: II
Product Code: JDK
Dated: April 30, 1999
Received: May 3, 1999

Dear Mr. Hoghaug:

This letter corrects our substantially equivalent letter of July 30, 1999.

We have reviewed your Section 510(k) 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally 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"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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

Indications for Use Page

510(k) Number (if known): K990345.

Device Name: RABEA™ Cement Restrictor Device

Indications for Use:

The RABEA™ 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.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990345

Prescription Use X
(Per 21 CFR 801.109)