K022729

NOV 14 2002

510(k) Summary

In accordance with the Food and Drug Administration Interim Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this is to serve as a 510(k) Summary for the Amedica Corp. Vented Cement Restrictor.

Submitter: Amedica Corp.
2116 South Lakeline Drive
Salt Lake City, UT 84109

Contact Person: Ashok C. Khandkar

Classification Name: CFR 878.3300 – Cement restrictor used in cemented applications for hip, knee and shoulder orthopedic surgery.

Common/Usual Name: Cement restrictor for cemented arthroplasty

Trade/Proprietary Name: Vented Cement Restrictor

Product Description:

The Vented Cement Restrictor used in cemented applications for hip, knee and shoulder arthroplasty, is a polymeric component manufactured from either medical grade injection molded polyethylene (ASTM F639-98a) or from 70:30 Polylactic Acid (Poly (L-lactide-co-D, L-lactide) amorphous (ASTM F1925-99e1).

Moreover, the subject Vented Cement Restrictor features a ball valve which safely vents air trapped distally to the stem, thus alleviating distal intra-medullary air pressure related embolisms.

Specific Diagnostic Indications:

The Vented Cement Restrictor is intended for use as a cement restrictor used in the treatment of the following:

- ❖ Total Hip Arthroplasty
- ❖ Total Knee Arthroplasty
- ❖ Total or Hemi Shoulder Arthroplasty

The device is not intended for use in spinal surgeries.

Substantial Equivalence:

Substantial equivalence determination is based on comparison of the Vented Cement Restrictor to the following legally marketed predicate competitive devices:

- Medtronic Sofamor Danek Cement Restrictor, K013663
- Polyethylene Medullary Plug, K811060
- Osteonics Cement Restrictor, K900462
- Polyethylene Medullary Plug, K830949
- Seidel Intramedullary Plug, K72205

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 14 2002

Ashok C. Khandkar
CEO
Amedica Corp.
2116 South Lakeline Drive
Salt Lake City, Utah 84109

Re: K022729
Trade/Device Name: Vented Cement Restrictor
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: JDK
Dated: August 8, 2002
Received: August 16, 2002

Dear Mr. Khandkar:

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 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" (21 CFR 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,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022729

Device Name: Vented Cement Restrictor

Indications For Use:

The Vented Cement Restrictor is intended for use as a cement restrictor used in the treatment of the following:

- Total Hip Arthroplasty
- Total Knee Arthroplasty
- Total or Hemi Shoulder Arthroplasty

The device is not intended for use in spinal surgeries.

for Mark N Milkerson

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

510(k) Number K022729

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use _____
(Per 21 CFR § 801.109) (Optional Format 1-2-96)