Cardo Medical
10 Clifton Blvd. Suite B1
Clifton, NJ 07011

JUL - 8 2010

Summary of Safety and Effectiveness

Submitter/Owner: Cardo Medical, Inc.
10 Clifton Blvd., Suite B1, Clifton, NJ 07011

Contact Person: Dina L. Weissman, J.D.
Director, Quality Assurance, Regulatory Affairs and Government Compliance
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Date Prepared: July 2, 2010

Trade Name: Cardo Medical Femoral Cement Obturator

Common Name: Cement Obturator

Classification Name: Surgical Mesh, (21 CFR 878.3300, Product Code: LZN, Class II) and Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis, (21 CFR 888.3560, Product Code: JWH, Class II)

Predicate Device: Howmedica Osteonics Tibial Tray Screw Hole Plugs (K032479)
Cardo Medical Inc. Total Knee System (K081127, cleared as ACCIN Total Knee System)

Device Description: The Cardo Medical Femoral Cement Restrictor is only intended for use with Cardo Medical PS femoral components (previously cleared in K081127). The device is an optional accessory and is manufactured from UHMWPE.

Intended Use: The Cardo Medical Cement Restrictor is for use at the option of the surgeon in total knee arthroplasty to occlude the opening in the femoral component to help prevent bone cement migration. Because the device may only be used in total knee arthroplasty, it carries the indications for use for the overall system:

The Cardo Medical Total Knee System is indicated for use in individuals undergoing surgery for:

- Painful, disabling joint disease of the knee resulting from degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis;
- Post-traumatic loss of knee joint configuration and function
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability;
- Revisions of previous unsuccessful knee replacement or other procedures.

Additional indications for posteriorly stabilized components:

- Ligamentous instability requiring implant bearing surfaces with increased constraint;
- Absent or non-functioning posterior cruciate ligament.

These devices are single use only and are intended for implantation with bone cement.

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Comparison to Predicates:

The Cardo Medical Femoral Cement Restrictor is an ultrahigh molecular weight polyethylene component for use in total knee arthroplasty. The device is substantially equivalent to the Howmedica Osteonics Tibial Tray Bone Screw Hole Plugs (K032479), having the same technological characteristics. The device and its predicate are composed of the same material, are used in total knee arthroplasty and serve the same purpose: to occlude the opening to help prevent bone cement from migrating.

Cardo Medical, Inc. has determined that any differences in the proposed device will not impact the safety or effectiveness of the total knee system for its intended use.

Synopsis of Test Methods and Results:
This 510(k) is for the addition of an optional non-load-bearing plug that does not change the worst case products for testing purposes; therefore the previous testing applies to these components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Cardo Medical, Inc.
% Ms. Dina L. Weissman, J.D.
Director, Quality Assurance
Regulatory Affairs and Government Compliance
10 Clifton Boulevard, Suite B1
Clifton, New Jersey 07011

Re: K101032
Trade/Device Name: Cardo Medical Total Knee System – Femoral Cement Restrictor
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Codes: JWH; LZN
Dated: April 13, 2010
Received: April 14, 2010

Dear Ms. Weissman:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K101032

Device Name: Cardo Medical Total Knee System - Femoral Cement Restrictor

INDICATIONS FOR USE

The Cardo Medical Total Knee System is indicated for use in individuals undergoing surgery for:

- Painful, disabling joint disease of the knee resulting from degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis;
- Post-traumatic loss of knee joint configuration and function
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability;
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Additional indications for posteriorly stabilized components:

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- Absent or non-functioning posterior cruciate ligament.

These devices are single use only and are intended for implantation with bone cement.

Prescription Use __XXX___ (Per 21 CFR 801 Subpart D)	OR	Over-The-Counter Use_____ (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)

Barbara Buchman

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101032