MAY 2 3 2012

510 (k) Summary

Contact: Rosemary Harry
Consultant
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Irvington, NY 10533
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914-357-2600

Date Prepared: May 16, 2012

Device Trade Name: Hemasorb®Resorbable Hemostatic Bone Putty

Manufacturer: Orthocon, Inc.
1 Bridge Street
Suite 121
Irvington, NY 10533

Common Name: Bone wax

Classification: None applicable

Class: Unclassified

Product Code: MTJ

Indications For Use:
Hemasorb Resorbable Hemostatic Bone Putty is indicated for use in the control of bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade. The material may be used during surgical procedures and in treating traumatic injuries. Hemasorb Resorbable Hemostatic Bone Putty is also indicated for use in the control of bleeding from bone surfaces in cardiothoracic surgery following sternotomy.

Device Description:
Orthocon Hemasorb Resorbable Hemostatic Bone Putty is a sterile, soft, moldable, biocompatible, absorbable material of putty-like consistency intended for use in the management of bleeding from the cut surface of bone. The material is a mixture of calcium stearate, Vitamin E acetate, and liquid surfactant. The material is virtually odorless, off-white in color and can be spread easily with minimal adhesion to surgical gloves. The bone putty requires no kneading prior to application and does not soften appreciably at body temperature.

When applied manually to surgically incised or traumatically broken bone, Hemasorb Resorbable Hemostatic Bone Putty achieves local control of bleeding by acting as a mechanical barrier (tamponade). The bone putty has been shown in animals to be dispersed and substantially absorbed within a period of 30 days.

Predicate Devices:
Hemasorb was shown to be substantially equivalent to previously cleared devices (K043260, K091121, K102762, and K102071).

Substantial Equivalence:
Hemasorb Resorbable Hemostatic Bone Putty is substantially equivalent to predicate devices in indications, intended use, design, materials, sterilization, and performance. Pre-clinical testing included animal testing in a sternotomy model.

Conclusion
Hemasorb was shown to be substantially equivalent to previously cleared devices with respect to its indications for use, design, function, and performance.

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

Orthocon Incorporated
% Ms. Rosemary Harry
Consultant
1 Bridge Street Suite 121
Irvington, New York 10533

MAY 2 3 2012

Re: K111575
Trade/Device Name: Hemasorb Resorbable Hemostatic Bone Putty
Regulation Class: Unclassified
Product Code: MTJ
Dated: May 16, 2012
Received: May 21, 2012

Dear Ms. Harry:

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

K111575

Indications for Use

510(k) Number (if known): K111575

Device Name: Hemasorb Resorbable Hemostatic Bone Putty

Hemasorb Resorbable Hemostatic Bone Putty is indicated for use in the control of bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade. The material may be used during surgical procedures and in treating traumatic injuries. Hemasorb Resorbable Hemostatic Bone Putty is also indicated for use in the control of bleeding from bone surfaces in cardiothoracic surgery following sternotomy.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MM

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

510(k) Number K111575