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4 510(k) Summary Of Safety And Effectiveness (Per 21 CFR 807.92)

General Company Information

Name:	Orthocon Inc.
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Date Prepared:	March 30, 2009

General Device Information

Product Name:	Orthostat™ Hemostatic Bone Putty
Classification:	Unclassified "Bone Wax", Product code: MTJ

Predicate Device

Device Name:	Orthostat™ Hemostatic Bone Putty
510(k) Number:	043260
Decision Date:	August 12, 2005
Decision:	Substantially Equivalent (SE)

Device Description

Orthocon Orthostat™ 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 (a wax-like tamponade), Vitamin E Acetate (for handling properties) and alkylene oxide copolymer (a dispersing agent). 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, Orthostat™ Hemostatic Bone Putty achieves local control of bleeding by acting as a mechanical barrier (tamponade). The bone putty will be dispersed and absorbed within a period of 60 days.

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Intended Use (Indications)

Orthocon Orthostat™ 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.

Substantial Equivalence

In this Special 510(k) submission the device is its own predicate. Orthostat™ Hemostatic Bone Putty is unchanged in its formulation from its predicate 510(k) clearance. The Indications for Use also remain unchaged. This Special 510(k) is to add the following contraindications to the labeling of the device.

> Do not use Orthostat in joints or in contact with synovial membrane or in procedures where the material will be in direct intra-articular contact with the joint (e.g. bunionectomy).
>
> Do not use Orthostat as a bone void filler or graft extender.

This Special 510(k) Notice contains revised Risk Management documents, summaries of biocompatibility testing and reports from investigations of the use of the device. Conformance to applicable Special Controls has been verified.

The data presented demonstrate the substantial equivalence of the modified device to the original device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Orthocon Corporation
% Dr. Kenneth A. Collins
675 US Highway One
North Brunswick, New Jersey 08902

APR 2 8 2009

Re: K091121
Regulatory Class: Unclassified
Product Code: MTJ
Dated: April 15, 2009
Received: April 17, 2009

Dear Dr. Collins:

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 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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.1 Orthostat™ Indications for Use

510(k) Number (if known): K091121

Device Name: Orthostat™ Hemostatic Bone Putty

Indications for Use:

Orthocon Orthostat™ 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.

Prescription Use ___X___ (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 MXM

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

510(k) Number K091121