510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(Per 21 CFR 807.92)

General Company Information

Name: Orthocon, LLC
Contact: Howard Schrayer
Regulatory Affairs Consultant

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Colts Neck, NJ 07722

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Date Prepared July 21, 2005

General Device Information

Product Name: OrthoStat™ Hemostatic Bone Putty

Classification: "Bone Wax", Product code: MTJ
Unclassified

Predicate Devices

CP Medical, Inc. - CP Medical Bone Wax
510(k) Number K024372

Ethicon, Inc. Bone Wax – Pre-enactment

United States Surgical Corporation Bone Wax
510(k) Number K971680
(Absorbable)

Ceremed AOC Bone Wax
510(k) Number K041363
(Absorbable)

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.

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

This submission supports the position that the Orthocon OrthoStat™ Hemostatic Bone Putty is substantially equivalent to a number of pre-enactment and previously cleared devices, including:

CP Medical Bone Wax - [501(k) Number K032930]
Lukens Bone Wax - [510(k) K791495]
Aesculap Bone Wax - [510(k) K000021]
Ethicon Bone Wax – Pre-enactment
United States Surgical Corporation Bone Wax – [510(k) Number K971680] (Absorbable)
Ceremed AOC Bone Wax - [510(k) Number K041363] (Absorbable)

The 510(k) Notice contains summaries of physical test results, functionality (efficacy testing) results, absorption testing and biocompatibility testing.

The data presented demonstrate that the device is biocompatible and is suitable for its indicated use. The single-patient-use OrthoStat™ Hemostatic Bone Putty is provided sterile.

Conclusions

Orthocon, LLC believes that the information provided establishes that similar legally marketed devices have been used for the same clinical applications as the Orthocon OrthoStat™ Hemostatic Bone Putty. The materials from which the Orthocon device is fabricated have an established history of use, and the devices have been tested in accordance with applicable FDA guidelines.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 1 2005

Mr. Howard L. Schrayer
Regulatory Affairs Consultant
Orthocon, LLC
167 Stone Hill Road
Colts Neck, New Jersey 07722

Re: K043260
Trade/Device Name: Orthocon, OrthoStat™ Hemostatic Bone Putty
Regulatory Class: Unclassified
Product Code: MTJ
Dated: July 22, 2005
Received: July 25, 2005

Dear Mr. Schrayer:

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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K043260

Device Name: Orthocon, OrthoStat™ Hemostatic Bone Putty

Indications For Use:

The 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 ✓ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Ruehl for Melkerson

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

510(k) Number K043260