K140117

510(k) SUMMARY
(Per 21 CFR 807.92)

FEB 1 1 2014

General Company Information

Name: Orthocon, Inc.
Contact: Howard Schrayer
Regulatory Affairs Consultant

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Date Prepared January 28, 2014

General Device Information

Product Name: AHBP*press*™ Absorbable Hemostatic Bone Putty

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

Predicate Device

Orthocon, Inc. – AHBP™ Absorbable Hemostatic Bone Putty
510(k) Number K122156

Description

Orthocon AHBP™ Absorbable Hemostatic Bone Putty is a sterile, soft, moldable, biocompatible, water soluble and absorbable material of putty-like consistency intended for use in the control of bleeding from bone surfaces by acting as a mechanical barrier or tamponade. The material is a mixture of alkylene oxide polymer-based materials and carboxymethylcellulose sodium salt. 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.

When applied manually to surgically incised or traumatically broken bone, AHBP™ Absorbable Hemostatic Bone Putty achieves local control of bleeding by acting as a mechanical barrier (tamponade). The bone putty will be dispersed and substantially absorbed within a period of 8 days.

Intended Use (Indications)

Orthocon AHBP*press*™ Absorbable Hemostatic Bone Putty is indicated for use as an absorbable implant material for the control of bleeding from bone surfaces.

Purpose of Submission

Orthocon intends to produce an alternate packaged configuration (strip) of its hemostatic bone putty as a product line extension to the AHBP™ Absorbable Hemostatic Bone Putty.

Substantial Equivalence

This submission supports the position that the Orthocon AHBP*press*™ Absorbable Hemostatic Bone Putty is substantially equivalent to a number of pre-enactment and previously cleared devices, and is exactly the same as the predicate Orthocon AHBP™ Absorbable Hemostatic Bone Putty with the exception of the packaging configuration.

Performance Data

Testing was conducted to verify the device's handling properties, to characterize the device's performance over a range of temperatures and to evaluate the device's dissolution and swelling properties. The following bench studies were completed: smearability stickiness, stiffness, temperature sensitivity, and dissolution and swelling.

Biocompatibility Testing

Testing was conducted to evaluate the device's biocompatibility in accordance with the recommendations of ISO 10993. The following biocompatibility studies were conducted on the final, finished, gamma-irradiation sterilized device and in accordance with the GLP requirements: cytotoxicity, irritation, sensitization, acute systemic toxicity, genotoxicity, implantation / subacute toxicity, hemolysis, and pyrogenicity. Sterile mesh used in the packaging of the strip was also evaluated for cytotoxicity.

In Vivo Performance Testing

Testing included animal studies to demonstrate intraoperative *in vivo* hemostasis, resistance to irrigation, ability to remove the device, and to characterize its safety and absorption time.

Conclusions

Orthocon, Inc. believes that the information provided establishes that similar legally marketed devices have been used for the same clinical applications as Orthocon AHBP*press*™ and that Substantial Equivalence to the predicate device has been established. The data presented demonstrate that the device is suitable for its indicated use. 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
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 11, 2014

Orthocon Incorporated
Mr. Howard Schrayer
Regulatory Affairs Consultant
1 Bridge Street, Suite 121
Irvinton, New York 10533

Re: K140117
Trade/Device Name: Orthocon AHBPpress™ Absorbably Hemostatic Bone Putty
Regulatory Class: Unclassified
Product Code: MTJ
Dated: January 14, 2014
Received: January 16, 2014

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. 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 contact 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. 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K140117

Device Name: Orthocon AHBP*press*™ Absorbable Hemostatic Bone Putty

Indications For Use:

Orthocon AHBP*press*™ Absorbable 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_____ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(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)

Jiyoung Dang -S