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

December 22, 2014

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

Re: K143069
Trade/Device Name: Hemasorbplus Press Resorbable Hemostatic Bone Putty
Regulatory Class: Unclassified
Product Code: MTJ
Dated: November 26, 2014
Received: November 28, 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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Binita S. Ashar -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143069

Device Name
Hemasorbplus Press Resorbable Hemostatic Bone Putty

Indications for Use *(Describe)*
Hemasorbplus 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY
(Per 21 CFR 807.92)

General Company Information

Name:	Orthocon, Inc.
Contact:	Howard Schrayer Regulatory Affairs Consultant
Address:	1 Bridge Street, Suite 121 Irvington, NY 10533
Telephone:	(609) 924 - 9510
Fax:	(914) 231 - 7884

Date Prepared October 24, 2014

General Device Information

Product Name: HEMASORB*PLUS press* Resorbable Hemostatic Bone Putty

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

Predicate Devices

Orthocon, Inc. - HEMOSTATIC BONE PUTTY 3 Resorbable Hemostatic Bone Putty
510(k) Number K123243

Orthocon, Inc. - AHBP*press*™ Absorbable Hemostatic Bone Putty
[510(k) Number K140117]

Description

Orthocon HEMASORB*PLUS press* Resorbable Hemostatic Bone Putty is a sterile, soft, moldable, biocompatible, resorbable material of putty-like consistency intended for use in the management of bleeding from the cut or damaged surface of bone. The material contains a mixture of alkylene oxide polymer based materials, vitamin E acetate, granular calcium phosphate and sodium carboxymethylcellulose. 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 damaged bone, HEMASORB*PLUS press* Resorbable Hemostatic Bone Putty achieves local control of bleeding by acting as a mechanical barrier (tamponade).

Intended Use (Indications)

Orthocon HEMASORB*PLUS press* 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.

Purpose of Submission

Orthocon intends to produce an alternate packaged configuration (strip) of its hemostatic bone putty as a product line extension to HEMOSTATIC BONE PUTTY 3 Resorbable Hemostatic Bone Putty.

Substantial Equivalence

This submission supports the position that the Orthocon HEMASORB*PLUS press* Resorbable 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 HEMOSTATIC BONE PUTTY 3 Resorbable Hemostatic Bone Putty [cleared under 510(k) K123243] with the exception of the shape and packaging configuration (i.e., a thin strip sandwiched between two layers of polypropylene mesh versus a cylindrical shape without a polypropylene mesh). The secondary predicate K140117 is a bone wax device that is packaged in the same strip configuration using the same packaging materials (including the polypropylene mesh) as this alternate configuration (HEMASORB*PLUS press*) of the device.

Testing Completed on Original Configuration

The following testing was completed on the original (predicate) device and is referenced in the 510(k) Notice because the device formulation is unchanged;

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

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.

Testing Completed on Strip Configuration

In accordance with design control procedures, Orthocon, Inc. performed a risk analysis for the proposed modifications based on an FMEA approach. Based on the results of the risk analysis, the following verification and validation activities were performed: cytotoxicity testing of the polypropylene mesh, USP and rabbit pyrogen testing, usability testing to verify
the device's handling properties, testing to evaluate product interface with the mesh, and package stability testing.

Conclusions
Orthocon, Inc. believes that the information provided establishes that similar legally marketed devices have been used for the same clinical applications as Orthocon HEMASORB*PLUS press* and that Substantial Equivalence to the predicate devices 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.