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

January 23, 2015

Hemostasis, LLC
Mr. Bernard Horwath
Hemostasis Regulatory Affairs
5000 Township Parkway
Saint Paul, Minnesota 55110

Re: K142348
Trade/Device Name: OsteoSeal® Bone Hemostat
Regulatory Class: Unclassified
Product Code: MTJ
Dated: December 23, 2014
Received: December 24, 2014

Dear Mr. Horwath:

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,

David Krause -S

for 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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K142348

Device Name
OsteoSeal® Bone Hemostat

Indications for Use *(Describe)*
OsteoSeal® Bone Hemostat is indicated for use in the control of bleeding from cut or damaged bone surfaces by acting as a mechanical barrier. The material may be used during surgical procedures or in treating traumatic injuries. OsteoSeal® Bone Hemostat is intended for use under the direction of a licensed healthcare provider.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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
OsteoSeal® Bone Hemostat

Date Prepared: August 20, 2014 (Revised Dec 12, 2014)

Submitter: Hemostasis, LLC
5000 Township Parkway
St. Paul, MN 55110
Telephone: 651- 855-1466
Fax: 651-855-1465

Contact: Mr. Bernard Horwath
Hemostasis Regulatory Affairs
St. Paul, MN 55110
Telephone: 651- 231-1761

Proprietary Name: OsteoSeal® Bone Hemostat

Common/Usual Name: Bone Wax

Classification Name: Bone Wax, Unclassified, Product Code MTJ

Establishment Registration Number: 3007225047

Description:
The Hemostasis OsteoSeal® Bone Hemostat stops bone bleeding by establishing a physical barrier along the edges of bones that have been damaged by trauma or cut during a surgical procedure. When applied as directed, OsteoSeal® forms a mechanical barrier that occludes the vascular openings in the damaged bone. This barrier prevents further bleeding during the surgical procedure.

OsteoSeal® is based upon known biodegradable polymeric chemistry that forms a ready-to-use bone hemostatic agent. OsteoSeal® Bone Hemostat consists of a dispersion of hydroxyapatite particles within a proprietary synthetic polylactic acid polymer. The material is virtually odorless, off-white in color and can be spread easily. OsteoSeal® is available in two forms: a bone hemostat ingot and a bone hemostat stick in an applicator. The bone hemostat ingot can be molded and formed by the surgeon to fit the damaged bone, while the applicator allows direct application of the bone hemostat to the bleeding area.

Indications for Use:
OsteoSeal® Bone Hemostat is indicated for use in the control of bleeding from cut or damaged bone surfaces by acting as a mechanical barrier. The material may be used during surgical procedures or in treating traumatic injuries.

OsteoSeal® Bone Hemostat is intended for use under the direction of a licensed healthcare provider.

Substantial Equivalence:
OsteoSeal® Bone Hemostat is substantially equivalent to the following predicate devices:

- Skeletal Kinetics CAAP Bone Wax K111538
- Synthes Hemostatic Bone Putty K113079
- Orthocon Orthostat Hemostatic Bone Putty/Applicator K091121/K102762
- Ethicon Bone Wax Preamendment

Biocompatibility:
Biocompatibility testing was performed using ISO 10993 – Biological Evaluation of Medical Devices and FDA guidance document Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices May 1, 1995 (G95-1), including Cytotoxicity, Sensitization, Irritation, Systemic Toxicity, Genotoxicity, Subchronic Implant and LAL testing. The OsteoSeal® Bone Hemostat and applicator comply with the biocompatibility requirements for its intended use.

Sterilization:
The OsteoSeal® Bone Hemostat is sterilized using a validated gamma radiation method to assure a sterility assurance level (SAL) of 10^{-6}. Packaging and Shelf Life testing were successfully completed.

Performance Testing:
Design verification testing and animal testing were performed for the OsteoSeal® Bone Hemostat to demonstrate physical and functional requirements were met. Design verification bench testing included appearance, handling and applicator function, and melt point. Animal performance testing in an acute porcine animal model test confirmed that OsteoSeal® Bone Hemostat met its product specifications for hemostasis and placement retention and performed at least as well, and in some cases better, than the standard commercially available bone wax control. In addition, a 13 week rabbit implant study confirmed the pathological safety of the OsteoSeal® Bone Hemostat, which demonstrated tissue irritation and bone healing results that were at least as good, and in some cases better, than the standard commercially available bone wax control.

Conclusion:
Through the data and information presented, Hemostasis, LLC, considers the OsteoSeal® Bone Hemostat substantially equivalent to the predicate devices already on the market (cleared by the 510(k) process) in terms of indications for use, scientific technology, design and functional performance and present no new concerns about safety and effectiveness.