November 29, 2016

InnoTherapy, Inc.
Robert Schiff, Ph.D., RAC, CQA, FRAPS
Schiff & Company, Inc.
1120 Bloomfield Ave.
West Caldwell, NJ 07006

Re: K161013
   Trade/Device Name: InnoSEAL Hemostatic Pad
   Regulatory Class: Class: Unclassified
   Product Code: FRO
   Dated: October 31, 2016
   Received: November 1, 2016

Dear Dr. Schiff:

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" (21 CFR 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
Indications for Use

InnoSEAL Hemostatic Pad is intended for the local management of bleeding wounds and for the promotion of rapid control of bleeding. InnoSEAL Hemostatic Pad is intended for use under the care of a healthcare professional.

The dressing is indicated for following wounds; lacerations, abrasions and the skin surface puncture sites for vascular procedures, percutaneous catheters/tubes.

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)

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) Premarket Notification for InnoSEAL Hemostatic Pad

InnoTherapy Inc.

510(k) Summary

(1) SUBMITTER:
InnoTherapy Inc.
Ace Hightechcity2, 25, Seonyu-ro 13-gil, Yeongdeungpo-gu,
Seoul, 07282 Republic of Korea
Telephone: +82 (2) 6959 1338
Contact person: Moon Sue Lee, CEO
Date prepared: October 31, 2016

(2) DEVICE NAME: InnoSEAL Hemostatic Pad
Trade Name: InnoSEAL Hemostatic Pad
Common Name: Topical Hemostasis Pad
Classification Name: Topical Wound Dressing Pad
Device Class: Unclassified
Product Code: FRO

(3) PREDICATE DEVICE: Substantial equivalence is based on following legally marketed devices.
- Clo-Sur Plus P.A.D (K032986 March 1, 2004)
- Coreleader Hemo Pad (K102944 September 7, 2011)

The predicates have not been subject to a design-related recall.
No reference devices were used in this submission.

(4) DESCRIPTION OF THE DEVICE: InnoSEAL Hemostatic Pad is a hydrophilic, lyophilized sponge pad for local management of bleeding wound made of proprietary formulation of chitosan and catechol conjugated chitosan which are biocompatible. InnoSEAL Hemostatic Pad is applied topically as an adjunct to manual compression. InnoSEAL Hemostatic Pad is a single use device individually packaged by PET mold and Aluminum lid and sterilized with gamma irradiation.

(5) INTENDED USE: InnoSEAL Hemostatic Pad is intended for the local management of bleeding wounds and for the promotion of rapid control of bleeding. InnoSEAL Hemostatic Pad is intended for use under the care of a healthcare professional.

The dressing is indicated for following wounds; lacerations, abrasions and the skin surface puncture sites for vascular procedures, percutaneous catheters/tubes.

InnoSEAL Hemostatic Pad has essentially the same intended use as the predicate device.

(6) TECHNOLOGICAL CHARACTERISTICS: InnoSEAL Hemostatic Pad is made of proprietary formulation of chitosan and catechol conjugated chitosan and is comprised of massively porous sponge. InnoSEAL Hemostatic Pad achieves the principal intended action of hemostasis by providing a physical barrier and effective
blood absorption to stop bleeding. Chitosan is a naturally occurring polysaccharide derived from shellfish. The natural biological property of chitosan carries cation (positively charged ion) that helps to stop external hemorrhage. In addition, catechol conjugated chitosan aids hemostasis by coating surface of bleeding area and forming a physical barrier enabling prompt control of bleeding and protection against foreign element contamination.
(7) COMPARISON WITH PREDICATE DEVICES: Following table is a comparison of our new InnoSEAL Hemostatic Pad and predicate devices.

<table>
<thead>
<tr>
<th></th>
<th>InnoSEAL Hemostatic Pad</th>
<th>Predicate 1 Clo-Sur Plus P.A.D. (K032986)</th>
<th>Predicate 2 Hemo-Pad (K102944)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product Code</strong></td>
<td>FRO</td>
<td>FRO</td>
<td>FRO</td>
</tr>
<tr>
<td><strong>Prescription/OTC</strong></td>
<td>Prescription</td>
<td>Prescription</td>
<td>Prescription</td>
</tr>
<tr>
<td><strong>Physical Composition</strong></td>
<td>a hydrophilic, lyophilized sponge pad made of proprietary formulation of chitosan and catechol conjugated chitosan</td>
<td>a soft, non-woven pad made of a proprietary formulation of poly-D-glucosamine and poly-N-acetylglucosamine derived from chitosan</td>
<td>a soft, non-woven topical pad made of poly-D-glucosamine and poly-N-acetylglucosamine derived from chitosan.</td>
</tr>
<tr>
<td><strong>Intended Use</strong></td>
<td>Local management of bleeding wounds and for the promotion of rapid control of bleeding. The dressing is indicated for following wounds; Lacerations, Abrasions and the skin surface puncture sites for vascular procedures, percutaneous catheters/tubes.</td>
<td>Local management of bleeding wounds and to provide a barrier to bacterial penetration of the dressing in all patients and for the promotion of rapid control (hemostasis) of bleeding in patients following hemodialysis and for those on anticoagulation therapy. The dressing is indicated for the following wounds: lacerations, abrasions, nose bleeds, and the skin surface puncture sites for vascular procedures, percutaneous catheters or tubes.</td>
<td>Topical wound management and for the external topical temporary control of moderate to severe bleeding. The dressing is indicated for the following wounds: abrasions, lacerations, skin surface puncture sites for vascular procedures (arteries and veins).</td>
</tr>
<tr>
<td><strong>Single Use Only</strong></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Biocompatibility</strong></td>
<td>Biocompatible</td>
<td>Biocompatible</td>
<td>Biocompatible</td>
</tr>
<tr>
<td><strong>Sterilization Method and Level</strong></td>
<td>sterilized by gamma-ray radiation to a 10⁶ SAL.</td>
<td>sterilized by E-beam radiation to a 10⁶ SAL.</td>
<td>sterilized by gamma-ray radiation to a 10⁶ SAL.</td>
</tr>
</tbody>
</table>

Use of chitosan as a hemostatic agent for the control of bleeding is the technical principle for both the subject and predicate devices. (K032986, K102944) It is based on the natural biological property of chitosan that carries cation (positively charged ion) that helps to stop external hemorrhage.
At a high level, the subject and predicate devices are based on the following same technological elements:

- Chitosan – used as a hemostatic agent
- Device applied topically as an adjunct to manual compression
- Topical pad – to absorb blood and wound exudates

The following technological differences exist between the subject and predicate devices:

- Use of catechol conjugated chitosan

InnoSEAL Hemostatic Pad has small quantity of catechol conjugated chitosan while predicate devices do not have. This slight difference is insignificant and does not affect the intended use and performance of the device. InnoSEAL Hemostatic Pad and its predicate devices are made from similar materials, utilize the same hemostatic mechanism, and have similar intended use.

(8) PERFORMANCE DATA: The following performance data has been provided in support of the substantial equivalence determination.

**Biocompatibility tests**

Biocompatibility tests were conducted following procedures outlined in the respective consensus standards, and results for InnoSEAL Hemostatic Pad met all relevant requirements in the test standards. The battery of testing included the following tests:

- Acute systemic toxicity
- Cytotoxicity
- Skin Sensitization
- Intracutaneous Reactivity
- Endotoxin

The intended use of the InnoSEAL Hemostatic Pad puts it within the biocompatibility category of limited contact duration, and breached/compromised surface device.

**Comparative liquid absorption test**

Liquid absorption test was conducted on the InnoSEAL Hemostatic Pad and the predicate device. Both hemostatic pads presented fast liquid absorption rates and liquid absorption capability of InnoSEAL Hemostatic Pad was equivalent to predicate device.

**Identification tests**

- Comparative FT-IR analysis of chitosan and InnoSEAL Hemostatic Pad
- Gelation test
Physical/Chemical tests

- Appearance
- Residue on ignition
- Degree of oxidation
- Loss on drying
- Heavy metal
- pH
- Residual solvent
- Deacetylation degree

Packaging tests

- Qualification test and evaluation of blister packaging machine
- Burst test
- Tensile / Tearing / Heat-sealing strength test
- Dye penetration test

Sterility and Shelf life tests

- Sterilization validation test
- Accelerated stability test
- Real-time stability test

Microbiological safety tests

Virus clearance tests were conducted to support adequacy of virus inactivation during the manufacture of InnoSEAL Hemostatic Pad. The studies demonstrated that efficient virus inactivation manufacturing steps are included with complete inactivation result of model viruses.

Animal tests

*In-vivo* hemostasis test using swine femoral artery hemorrhage model was performed to demonstrate the effectiveness and safety of InnoSEAL Hemostatic Pad. In study 15-KE-136, InnoSEAL Hemostatic Pad and predicate device showed superior hemostatic efficacy compared to manual compression with regular gauze. Gross necropsy and histopathological evaluations were similar and comparable between the groups. In overall, InnoSEAL Hemostatic Pad was effective and shortened the time to hemostasis at injured femoral artery access sites. InnoSEAL Hemostatic Pad was safe and effective for its intended use.
The collective results of the bench and animal testing demonstrate that the materials chosen, the manufacturing process, and the design of the InnoSEAL Hemostatic Pad meet the established specifications necessary for the consistent performance during its intended use. In addition, the tests demonstrate that the InnoSEAL Hemostatic Pad does not raise new questions of effectiveness or safety for its intended use when compared to the predicate devices.

(9) CONCLUSION: Based on the comparison of intended use, design, materials, and performance, InnoSEAL Hemostatic Pad is substantially equivalent to legally marketed predicate devices and is safe and effective for its intended use.