May 19, 2022

Hemostasis LLC
Lakshmi Ganesh Bollina
Regulatory Associate
5000 Township Pkwy
St Paul, Minnesota 55110

Re: K210411
Trade/Device Name: PosiSep® EAR Fragmentable Ear Dressing
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, nose, and throat synthetic polymer material
Regulatory Class: Class II
Product Code: NHB

Dear Lakshmi Ganesh Bollina:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated May 5, 2022. Specifically, FDA is updating this SE Letter to change the trade name from "PosiSep ME Fragmentable Ear Dressing" to "PosiSep® EAR Fragmentable Ear Dressing" as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Shu-Chen Peng, OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices, 301-796-6481, shu-chen.peng@fda.hhs.gov.

Sincerely,

Shuchen Peng -S

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

May 5, 2022

Hemostasis LLC
Lakshmi Ganesh Bollina
Regulatory Associate
5000 Township Pkwy
St Paul, Minnesota 55110

Re: K210411
Trade/Device Name: PosiSep ME Fragmentable Ear Dressing
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, Nose, And Throat Synthetic Polymer Material
Regulatory Class: Class II
Product Code: NHB
Dated: April 6, 2022
Received: April 7, 2022

Dear Lakshmi Ganesh Bollina:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shuchen Peng -S

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210411

Device Name

PosiSep® EAR Fragmentable Ear Dressing

Indications for Use *(Describe)*

PosiSep® EAR Fragmentable Ear Dressing is indicated for use in patients undergoing outer ear surgery:

As a space occupying stent to separate and prevent adhesions between mucosal surfaces; and

To help control minimal bleeding following surgery or trauma by tamponade effect, blood absorption and platelet aggregation.

PosiSep® Ear 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(k) Summary

PosiSep® EAR Fragmentable Ear Dressing

Date Prepared: 03 May 2022

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

Contact: Mr. Lakshmi Ganesh Bollina
Hemostasis Regulatory Affairs Associate
5000 Township Parkway
St. Paul, MN 55110
Telephone: 480- 579-1239
Fax: 651-855-1465

Proprietary Name: PosiSep® EAR Fragmentable Ear Dressing

Common/Usual Name: Fragmentable Ear Dressing

Classification Name: ENT Synthetic Polymer Material
Product Code – NHB, Class II, 21 CFR 874.3620

Predicate Device: NasoPore® K070715

Reference Devices: PosiSep/PosiSep X K120958/K122494

Establishment Registration Number: 3007225047

Description:
The Hemostasis PosiSep® EAR Fragmentable Ear Dressing is a sterile dressing comprised of modified Chitosan particles and polysaccharide binder. Chitosan has well known hemostasis properties and when combined with hydroxyethyl cellulose binder, forms a foam-type dressing that has an affinity to absorb and hold water. PosiSep® EAR Fragmentable Ear Dressing is used in patients undergoing outer ear surgery as a space occupying stent and to help control minimal bleeding. The dressing quickly dehydrates blood, thereby causing rapid hemoconcentration of platelets, serum proteins and fibrinogen, leading to clotting that limits and controls bleeding and edema.

PosiSep® EAR is fragmentable and eliminated from the site of application by natural excretion via the ear canal.

Indications for Use:

PosiSep® EAR Fragmentable Ear Dressing is indicated for use in patients undergoing outer ear surgery:

- As a space occupying stent to separate and prevent adhesions between mucosal surfaces; and
- To help control minimal bleeding following surgery or trauma by tamponade effect, blood absorption and platelet aggregation.

PosiSep® EAR is intended for use under the direction of a licensed healthcare provider.

Comparison with Predicates:

The PosiSep® EAR Fragmentable Ear Dressing is substantially equivalent to the primary predicate, the Nasopore® Ear, for the following reasons:

- Both have the same FDA Classification, Indications for Use.
- Both are sterile, single use devices that are indicated for use in patients undergoing outer ear surgery.
- Both contain materials proven biocompatible for their intended use in accordance with ISO 10993-1.
- Both are provided in foam configurations and both fragment in equivalent time intervals sufficient for the intended use.

The differences between the subject device PosiSep® EAR and NasoPore® EAR are not critical to the intended use of the device, and do not affect the safety and effectiveness of the subject device when used as labeled. Both the subject and predicate devices are indicated to separate and prevent adhesions between mucosal surfaces and to control minimal bleeding following surgery.

The primary differences appear to be the composition of the Ear Dressing and the sterilization method.

- Dressing composition: PosiSep® EAR uses an animal sourced Chitosan that is derivatized to include Carboxymethyl groups and Nasopore® Ear contains a synthetic sourced Poly(DL-lactide-co-e-caprolactone) urethane. Both are effective to separate and prevent adhesions between mucosal surfaces and to control minimal bleeding following surgery and biocompatible.
- Sterilization Method: PosiSep® EAR uses the gamma radiation sterilization method and Nasopore® Ear uses Ethylene Oxide (EtO) Sterilization method.

The table below provides a comparison of PosiSep® EAR with Nasopore® Ear.

Substantial Equivalence Comparison to Predicate Device

Parameter	PosiSep® EAR Fragmentable Ear Dressing	Nasopore® Ear Fragmentable Ear Dressing	Comparison
Classification Name	ENT Synthetic Polymer Material, Class II Product Code NHB	ENT Synthetic Polymer Material, Class II Product Code NHB	Same
Indications for Use	PosiSep® EAR is a fragmentable ear dressing and is indicated for use in patients undergoing outer ear surgery: • As a space occupying stent to separate and prevent adhesions between mucosal surfaces; and • To help control minimal bleeding following surgery or trauma by tamponade effect, blood absorption and platelet aggregation. PosiSep® EAR is intended for use under the direction of a licensed healthcare provider.	Nasopore® Ear is a fragmentable ear packing and is indicated for use in patients, undergoing ear surgery, as a space occupying stent to separate and prevent adhesions between mucosal surfaces; to help control minimal bleeding, following ear surgery, by tamponade effect and blood absorption	Same
Supplied Sterile	Gamma Sterilized	EtO Sterilized	Different methods but both devices are supplied sterile
Single-use/Reusable	Single-use	Single-use	Same
Material Composition	Carboxymethyl Chitosan and Hydroxyethyl Cellulose	Poly(DL-lactide-co-e-caprolactone) urethane	Different material composition but both are effective.
Packaging	PET/Foil Pouch	Single use, blister, cardboard box	Equivalent

	Cardboard Carton		
Biocompatibility	Biocompatible (10993-1)	Biocompatible (10993-1)	Same

In addition, the PosiSep® EAR Fragmentable Ear Dressing is same as the Hemostasis PosiSep® Family Hemostat Dressings/Intranasal Splints in terms of:

- Material composition
- Mechanism of action
- Manufacturing
- Sterilization
- Packaging/Distribution

The only difference between PosiSep® EAR and the other PosiSep® Family devices is the compression of the device before packaging.

- PosiSep® EAR devices are not compressed before packaging where the other PosiSep® Family devices are compressed before packaging.

Due to the differences in Intended Use PosiSep® EAR Fragmentable Ear Dressing has undergone additional biocompatibility testing based on the relevant endpoints defined by ISO 10993-1:2018 and the FDA: Use of International Standard ISO 10993, Biological evaluation of medical devices Part 1: Evaluation and Testing as a surface device with breached or compromised contacting device.

The table below provides a comparison of PosiSep® EAR Fragmentable Ear Dressing with Reference Devices .

Comparison to Reference Device

Parameter	PosiSep® EAR Fragmentable Ear Dressing	PosiSep® Family Hemostat Dressings/Intranasal Splints	Comparison
Indications for Use	PosiSep® EAR is a fragmentable ear dressing and is indicated for use in patients undergoing outer ear surgery: • As a space occupying stent to separate and prevent adhesions between mucosal surfaces; and • To help control minimal bleeding following surgery or trauma by tamponade effect, blood absorption and platelet aggregation. PosiSep® EAR is intended for use under the direction of a licensed healthcare provider.	PosiSep®/ PosiSep® X Hemostat Dressings/Intranasal Splints are indicated for use in patients undergoing nasal/sinus surgery as a space occupying hemostat/splint to: • Separate tissue or structures compromised by surgical trauma; • Separate and prevent adhesions between mucosal surfaces during mesothelial cell regeneration in the nasal cavity; • Help control minimal bleeding following surgery or trauma; • Help control minimal bleeding following surgery or nasal trauma by tamponade effect, blood absorption and platelet aggregation; and • Act as an adjunct to aid in the natural healing process. PosiSep®/ PosiSep® X are indicated for use as a nasal hemostat to treat epistaxis. PosiSep®/ PosiSep® X are intended for use under the direction of a licensed healthcare provider.	All Devices are indicated for use as Space occupying stents to separate tissue and help control minimal bleeding. PosiSep EAR is indicated for Outer Ear surgery, while the currently marketed PosiSep Devices are Nasal/Sinus Dressings

Mechanism of Action	Blood dehydration and concentration of serum proteins, platelets and fibrinogen leading to clotting	Blood dehydration and concentration of serum proteins, platelets and fibrinogen leading to clotting	Same
Supplied Sterile	Gamma Sterilized	Gamma Sterilized	Same
Single-use/Reusable	Single-use	Single-use	Same
Material Composition	Carboxymethyl Chitosan and Hydroxyethyl Cellulose	Carboxymethyl Chitosan and Hydroxyethyl Cellulose	Same
Compression	No	Yes	Leck of compression is specific for Ear Use.
Packaging	PET/Foil Pouch Cardboard Carton	PET/Foil Pouch Cardboard Carton	Same
Biocompatibility	Biocompatible: • Non-cytotoxic • Non-Irritating (Intracutaneous) • Non-Sensitive • Non-Pyrogenic • Non-Toxic (Acute Systemic Toxicity)	Biocompatible: • Non-Cytotoxic • Non-Irritating (Intracutaneous) • Non-Sensitive	Same

Biocompatibility:
Biocompatibility testing was performed using the guidelines of ISO 10993 – Biological Evaluation of Medical Devices and FDA guidance document Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices. The PosiSep® EAR Fragmentable Ear Dressing passed biocompatibility requirements for their intended use.

Sterilization, Packaging, Shelf Life:
The PosiSep® EAR Fragmentable Ear Dressing are sterilized using the same validated gamma radiation method as the PosiSep® family of devices to assure a sterility assurance level (SAL) of 10^{-6}. The packaging/distribution and shelf-life are same as the PosiSep family of devices.

Performance Bench Testing:
Design verification testing was performed on PosiSep® EAR Fragmentable Ear Dressing to demonstrate physical and functional requirements were met.

Conclusion:
Through the data and information presented, Hemostasis, LLC considers the PosiSep® EAR Fragmentable Ear Dressing substantially equivalent to the Nasopore Ear Predicate device already in the market (cleared by the 510(k) process) in terms of indications for use, scientific technology, design, and functional performance and is supported by the reference predicate device. PosiSep EAR presents no new concerns about safety and effectiveness and is suitable for its intended use.