December 1, 2022

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

Re: K220326
Trade/Device Name: PosiSep X BAM Hemostat Dressing/Intranasal Splint
Regulation Number: 21 CFR 874.4100
Regulation Name: Epistaxis balloon
Regulatory Class: Class I
Product Code: EMX, LYA

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 November 14, 2022. Specifically, FDA is updating this SE Letter to address a typographical error in the regulatory classification and removal of confidential text in the 510(k) Summary 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, Ph.D., 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

November 14, 2022

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

Re: K220326
Trade/Device Name: PosiSep X BAM Hemostat Dressing/Intranasal Splint
Regulation Number: 21 CFR 874.4100
Regulation Name: Epistaxis Balloon
Regulatory Class: Class I
Product Code: EMX, LYA
Dated: October 14, 2022
Received: October 17, 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,

Joyce C. Lin -S

for 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)*
K220326

Device Name
PosiSep® X BAM Hemostatic Dressing/Intranasal Splint

Indications for Use *(Describe)*
PosiSep® X BAM Hemostat Dressing/Intranasal Splint is 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® X BAM is indicated for use as a nasal hemostat to treat epistaxis.
PosiSep® X BAM 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.

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

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Food and Drug Administration
Office of Chief Information Officer
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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

PosiSep® X BAM Hemostatic Dressing/Intranasal Splint

Date Prepared: 14 November 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® X BAM Hemostatic Dressing/Intranasal Splint

Common/Usual Name: Nasal Hemostat and Intranasal Splint

Classification Name: Epistaxis Balloon (21 CFR 874.4100)

Regulatory Class: I

Product Code: EMX, LYA

Predicate Device:	Hydrofera Bacteriostatic Nasal Dressing	K983276
Reference Devices:	PosiSep®/PosiSep® X	K122494
	Hydrofera Blue Ready	K190268

Establishment Registration Number: 3007225047

Description:
The Hemostasis PosiSep® X BAM is placed in the nasal cavity after sinus surgery to prevent adhesions, control mild bleeding, and provide a level of protection against bacteria and fungi. PosiSep X BAM is supplied as a compressed foam, and it quickly dehydrates blood, thereby causing rapid hemoconcentration of platelets, serum proteins and fibrinogen, leading to clotting that limits and controls bleeding and edema. Upon hydration, PosiSep® X BAM expands to contact and conform to the surrounding anatomy.
PosiSep X BAM is comprised of N, O-Carboxymethyl Chitosan derived from non-shell fish based Chitosan, modified Cellulose, and antimicrobial agents.

PosiSep® X BAM is fragmentable and eliminated from the site of application by natural excretion through the action of cilia.

Indications for Use:
PosiSep® X BAM Hemostat Dressing/Intranasal Splint is 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® X BAM is indicated for use as a nasal hemostat to treat epistaxis.

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

Substantial Equivalence:
PosiSep® X BAM Hemostat Dressing/Intranasal Splint is substantially equivalent in intended use and performance characteristics to Hydrofera Bacteriostatic Nasal Dressing, 510(k) Number K983276 (EMX), clearance date 09/14/1999, for the following reasons:

Both devices are nasal dressings with the same intended use. The intended use for these products is that the devices are intended for use after nasal/sinus surgery as nasal dressings. Nasal Dressings are commonly used following endoscopic nasal/sinus surgery to prevent ongoing minimal bleeding and to facilitate the wound healing process. The predicate device and the proposed new device share this same general intended use, defined as the general purpose of the device or its function, and encompass the indications for use in nasal/sinus surgery to control bleeding and provide tissue separation for proper healing.

The differences between the indications of use for the subject device PosiSep® X BAM and Hydrofera Bacteriostatic Nasal Dressing 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 in the nasal cavity, and to control minimal bleeding following surgery or nasal trauma by the tamponade effect and blood absorption.

The subject device PosiSep® X BAM has some specific indications for use in addition to those for Hydrofera Bacteriostatic Nasal Dressing. These indications describe the condition the device will treat or mitigate, including separating structures compromised by surgical trauma, controlling minimal bleeding by platelet aggregation, and use as a nasal packing to treat

epistaxis. These indications are matched by the reference device PosiSep/PosiSep X and commonly used in nasal dressing indications for use.

PosiSep® X BAM and Hydrofera Bacteriostatic Nasal Dressing have many of the same technological characteristics but are made from different base materials. The subject device PosiSep® X BAM is made of a combination of N, O – Carboxymethyl Chitosan derived from a non-shell fish source, modified cellulose and antimicrobial agents, while the Hydrofera Bacteriostatic Nasal Dressing is made of absorbent polyvinyl alcohol (PVA) and antimicrobial agents. Both materials provide a foam substrate suitable for its mechanism of action and intended use. The materials in both devices passed the appropriate Biocompatibility testing. Antimicrobial performance testing (described below) shows that the subject device PosiSep® X BAM performs equivalently to the predicate device Hydrofera Bacteriostatic Nasal Dressing. Both devices are sterile, single use and provided in appropriate packaging.

Biocompatibility:
Biocompatibility testing was performed using ISO 10993 Biological Evaluation of Medical devices and FDA guidance document " Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process", issued September 4, 2020. The PosiSep® X BAM Hemostat Dressing/Intranasal Splint complies with the biocompatibility requirements for its intended use.

Sterilization, Packaging, Shelf Life:
PosiSep® X BAM is sterilized using a validated gamma radiation method to assure a sterility assurance (SAL) of 10^{-6}. The packaging and distribution of PosiSep X BAM are the same as currently marketed PosiSep devices. Shelf life testing was performed on the sterile product according to the applicable standards and guidance documents.

Performance Bench Testing:
Design verification testing was performed for the PosiSep® X BAM Hemostat Dressing/Intranasal Splint to demonstrate physical and functional requirements were met.

PosiSep® X BAM demonstrated greater than 4 log antimicrobial activity against a wide range of gram positive bacteria, gram negative bacteria, and fungal strains, including strains with known resistance to antibiotics: devices inoculated with bacteria and fungi demonstrated a complete absence of viable cells for up to 7 days.

Antimicrobial Information:
The antimicrobial effectiveness of PosiSep® X BAM was tested against the following microbial strains and no viable cells were observed at any time point. The table below outlines the timeframe in which PosiSep® X BAM demonstrated antimicrobial activity to the tested microbial strains. **Note:** A correlation between in vitro testing and clinical effectiveness has not been established.

Table 1 PosiSep® X BAM Antimicrobial Activity Timeline

Bacterial Strain (Gram Positive)	**ATCC**	**24 hours**	**48 hours**	**7 days**
Staphylococcus aureus	6538	>4 log removal →		
Staphylococcus aureus (MRSA)	33591	>4 log removal →		
Streptococcus pneumoniae	6301	>4 log removal →		
Bacterial Strain (Gram Negative)	**ATCC**	**24 hours**	**48 hours**	**7 days**
Pseudomonas aeruginosa	9027	>4 log removal →		
Moraxella catarrhalis	25240	>4 log removal →		
Klebsiella pneumoniae	4352	>4 log removal →		
Fungi Strain	**ATCC**	**24 hours**	**48 hours**	**7 days**
Aspergillus brasiliensis	16404	>4 log removal →		
Candida albicans	10231	>4 log removal →		

Conclusion:
Utilizing FDA's Guidance for Industry and FDA Staff "Format for Traditional and Abbreviated 510(k)s" issued on September 13, 2019, a comparison of key characteristics demonstrates that the proposed device PosiSep® X BAM Hemostat Dressing/Intranasal Splint is substantially equivalent to the predicate device in terms of intended use and performance characteristics. The PosiSep® X BAM is as safe, as effective, and performs as well as the predicate device.

The substantial equivalence analysis supports that the PosiSep® X BAM Hemostatic Dressing/Intranasal Splint presents no new concerns about safety and effectiveness and is suitable for its intended use.