K122494

510(k) Summary
PosiSep™ and PosiSep™ X Hemostat Dressing/Intranasal Splint

MAR 27 2013

Date Prepared: August 15, 2012
March 8, 2013 Updated

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
5000 Township Parkway
St. Paul, MN 55110
Telephone: 651- 231-1761
Fax: 651-855-1465

Proprietary Name: PosiSep™ and PosiSep™ X Hemostat Dressing/Intranasal Splint

Common/Usual Name: Nasal Hemostat and Intranasal Splint

Classification Name: Intranasal Splint, Class I, Product Code LYA
ENT Epistaxis Hemostat, Class I, Product Code EMX

Establishment Registration Number: 3007225047

Description:
The Hemostasis PosiSep™ and PosiSep™ X Hemostat Dressing/Intranasal Splint are sterile hemostats comprised of modified Chitosan particles and polysaccharide binders. Chitosan has well known hemostasis properties and, when combined with carboxymethylcellulose and hydroxyethylcellulose binders, forms a foam-type dressing that has an affinity to absorb and hold water. PosiSep™ and PosiSep™ X Hemostat Dressing/Intranasal Splint have the identical material composition as the currently market cleared Hemostasis PosiSep™ and PosiSep™ X Topical Hemostat. The PosiSep™ and PosiSep™ X Hemostat Dressing /Intranasal Splint are used for topical wounds and placed in the nasal cavity after surgery or trauma for the treatment of bleeding and as a space occupying stent to separate sinus tissue and prevent adhesions between mucosal surfaces. The dressings quickly dehydrate blood, thereby causing rapid hemoconcentration of platelets, serum proteins and fibrinogen, leading to clotting that limits and controls bleeding and edema.

PosiSep™ and PosiSep™ X are removed from the sight of application by natural excretion and routine flushing to eliminate the material from the nasal cavity and avoid the issues involved with physical removal of a non-fragmenting dressing.

Indications for Use:
PosiSep™ and PosiSep™ X Hemostat Dressing/Intranasal Splint 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™ and PosiSep™ X are indicated for use as a nasal hemostat to treat epistaxis.

PosiSep™ and PosiSep™ X are intended for use under the direction of a licensed healthcare provider.

Substantial Equivalence:
The PosiSep™ and PosiSep™ X Hemostat Dressing/Intranasal Splint are substantially equivalent to the following predicate devices:

- Hemostasis PosiSep™ and PosiSep™ X Topical Hemostat K120958
- CogENT Therapeutics Nasal/Epistaxis Pack K113585
- MeroGel Nasal Dressing and Sinus Stent K982731
- MeroPack Nasal Dressing and Sinus Stent K041381

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). The PosiSep™ and PosiSep™ X Hemostat Dressing/Intranasal Splint comply with the biocompatibility requirements for their intended use.

Sterilization:
The PosiSep™ and PosiSep™ X Hemostat Dressing/Intranasal Splint are sterilized using a validated gamma radiation method to assure a sterility assurance level (SAL) of 10^{-6}.

Performance Bench Testing:
Design verification testing was performed for the PosiSep™ and PosiSep™ X Hemostat Dressing/Intranasal Splint to demonstrate physical and functional requirements were met. Animal and bench testing demonstrated appropriate hemostatic and tissue separation properties, respectively, to assure effectiveness for their intended use.

Conclusion:
Through the data and information presented, Hemostasis, LLC, considers the PosiSep™ and PosiSep™ X Hemostat Dressing/Intranasal Splint 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.

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

March 27, 2013

Hemostasis, LLC
% Mr. Bernard Horwath
Consultant to Hemostasis, LLC
5000 Township Parkway
Saint Paul, MN 55110

Re: K122494
Trade/Device Name: PosiSep™ and PosiSep X™ Hemostat Dressing/Intranasal Splint
Regulation Number: 21 CFR 874.4780
Regulation Name: Intranasal Splint
Regulatory Class: Class I
Product Code: LYA, EMX
Dated: March 8, 2013
Received: March 11, 2013

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Eric A. Mann

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4.0 Indications for Use Statement

510(k) Number (if known): K122494

PosiSep™ and PosiSep™ X Hemostat Dressing/Intranasal Splint:

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PosiSep™ and PosiSep™ X Hemostat Dressing/Intranasal Splint are indicated for use in patients undergoing nasal/sinus surgery as a space occupying hemostat/splint to:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Office of Device Evaluation (ODE)

Daniel C. Clupper
2013.03.25 17:06:48 -04'00'

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices

510(k) Number K122494