DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 23, 2014

Polyganics BV
Ms. Betty IJmker
Manager QA/RA
Rozenburglaan 15a
9727 DL Groningen
The Netherlands

Re: K141816
Trade/Device Name: Hemopore
Regulation Number: 21 CFR 874.4780
Regulation Name: Intranasal Splint
Regulatory Class: Class I
Product Code: LYA
Dated: September 18, 2014
Received: September 23, 2014

Dear Ms. IJmker,

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,

Eric A. Mann -S

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141816

Device Name
HEMOPORE®

Indications for Use *(Describe)*
HEMOPORE® is intended for use in patients undergoing nasal/sinus surgery as a temporary wound dressing. HEMOPORE® functions as a topical hemostatic aid to control mild bleeding by tamponade effect, blood absorption, platelet activation and aggregation.
It acts as an adjunct to aid in the natural healing process as a space occupying stent to separate and support tissues. It prevents adhesions and minimizes edema.

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.

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510(k) Summary of Safety and Effectiveness
K141816

Submitter
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Date Prepared: July 2, 2014

General Provisions:

Trade Name:	HEMOPORE®
Common Name:	Hemostatic Nasal Dressing
Classification Name:	Intranasal splint
CFR Section:	21 CFR 874.4780
Product Code:	LYA
Device Class:	Class I

Predicate Devices:
K052099 - Nasopore® nasal dressing
K122494 - PosiSep™ and PosiSep™ X Hemostat Dressing/Intranasal Splint

Performance Standards: None

Device Description
HEMOPORE® is a sterile fragmentable nasal dressing of 8 cm composed of poly(DL-lactide-co-ε-caprolactone) urethane and blended with a chitosan derivate and a violet color additive.

After insertion of HEMOPORE® in the nasal cavity, fluids will be absorbed by the dressing, which helps to control bleeding after surgery.

The dressing fragments within several days by hydrolyzing ester bonds, whereafter it is drained from the nasal cavity via the natural mucus flow.

The HEMOPORE® is sterilized in a blister package. The device is single-use, cannot be re-sterilized, and is a prescription product.

Indications for Use

HEMOPORE® is intended for use in patients undergoing nasal/sinus surgery as a temporary wound dressing.
HEMOPORE® functions as a topical hemostatic aid to control mild bleeding by tamponade effect, blood absorption, platelet activation and aggregation.
It acts as an adjunct to aid in the natural healing process as a space occupying stent to separate and support tissues. It prevents adhesions and minimizes edema.

Comparison of technological characteristics with the predicate device

The technological principle is based on the use of nasal dressings as a space-occupying device in the nasal and sinus cavities after nasal and sinus surgery. The predicate devices, NASOPORE® and POSISEP®, as well as the subject device HEMOPORE®, have the same technological principle as HEMOPORE®: to function as a temporary wound dressing, controlling mild bleeding by tamponade effect and blood absorption. The subject device and the predicate devices are made from fragmentable biomaterials, meaning that the material is spontaneously cleared from the nasal cavities.

The technological difference between the subject and predicate devices is the addition of a color additive in the subject device, but this does not raise issues of safety and effectiveness.

HEMOPORE shares the same indications for use, device operation, and overall technical and functional capabilities, and therefore is substantially equivalent to the predicate devices for use as a space-occupying stent/packing for nasal/sinus use. Additionally, performance test data has demonstrated at least adequate device performance.

Performance data

Biocompatibility testing

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). HEMOPORE® complies with the biocompatibility requirements for their intended use.

Bench testing

The following in vitro testing demonstrated that the technological characteristics and performance criteria of HEMOPORE® were met:

- Degradation test
- Shelf-life test
- Absorption test

Thrombogenicity testing was performed to compare the predicate devices with the subject device. The data demonstrated that HEMOPORE® has appropriate hemostatic properties to assure effectiveness for its intended use and performs in a manner that is at least equivalent to the predicate devices.

Summary of substantial equivalence

The results of all testing conducted demonstrate that the HEMOPORE® device is substantially equivalent to its predicate devices NASOPORE®, POSISEP™, and POSISEP™-X, in terms of indications for use, technological characteristics and design, and presents no concerns about safety and/or effectiveness.

It can be concluded that HEMOPORE® is as safe, as effective, and performs at least equivalent to its predicate devices.