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

August 7, 2014

Ms. Betty Ijmker
Manager QA/RA
c/o Polyganics Bv
Rozenburglaan 15A
GRONINGEN, NL 9727-DL

Re: K141423
Trade/Device Name: Nasopore-fd
Regulation Number: 21 CFR 874.4780
Regulation Name: Intranasal Splint
Regulatory Class: Class I
Product Code: LYA
Dated: July 8, 2014
Received: July 14, 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" (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 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

Indications for Use Statement

510(k) Number	K
Device Name	NASOPORE® FD nasal dressing
Indications for Use	NASOPORE® FD is a fragmentable nasal dressing and is indicated for use in patients undergoing nasal/sinus surgery as a space occupying stent to separate and prevent adhesions between mucosal surfaces; to help control minimal bleeding following surgery or nasal trauma by tamponade effect and blood absorption.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____x____ OR Over The Counter Use_____
(Per 21 CFR 801. 109)

Vasant G.
Malshet -S

Special 510(k) Summary of Safety and Effectiveness
Line extension to NASOPORE® nasal dressing

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Date Prepared: 27 May 2014

General Provisions:

Trade Name:	NASOPORE® FD Nasal Dressing
Common Name:	Nasal Dressing
Classification Name:	Intranasal splint
Regulatory class:	Class I
Regulation #	21CFR874.4780
Product code:	LYA

Predicate Device:	Nasopore	Polyganics BV	K052099

Performance Standards: For the performance of intranasal splints, the FDA, under section 514 of the Food, Drug and Cosmetic Act, has not established standards.

Indications for Use: NASOPORE® FD is a fragmentable nasal dressing and is indicated for use in patients undergoing nasal/sinus surgery as a space occupying stent to separate and prevent adhesions between mucosal surfaces; to help control minimal bleeding following surgery or nasal trauma by tamponade effect and blood absorption.

Device Description

NASOPORE® FD is composed of a bioresorbable poly(DL-lactide-co-ε-caprolactone) urethane that fragments within several days after insertion in the nasal cavity, whereafter it is drained from the nasal cavity via the natural mucus flow.

The NASOPORE® FD size and type are indicated on the label and are packed in a blister. NASOPORE® FD is indicated for single-use.

The modification in this submission concerns a line extension to the predicate device NASOPORE® with a NASOPORE® FD that fragments faster than the cleared predicate device.

Performance Data:

In vitro testing for this line extension demonstrated that the technological characteristics and performance criteria of the additional NASOPORE type are comparable to the currently cleared NASOPORE nasal dressing and that they can perform in a manner equivalent to NASOPORE devices currently on the market for the same intended use. The results of the in vitro testing are summarized below:

Properties	Method	Current NASOPORE®	**New NASOPORE® FD**
Shape integrity (shape intact in saline at 37°C)	Visual	>36 hour(in Saline)	>36 hour (in Saline)
Fragmentation time (In saline at 37°C)	Fragmentation test	96hours	48 hours
Compression	Compressive strength measurement	>3 kPa (Firm)	>3 kPa
Porosity	Porosity measurement	95-98 %	95-98 %
Color	Visual	Off-white	Blue/Green
IV (intrinsic viscosity)	IV measurement	IV ≥ 0.8 dl/g	IV ≥ 0.8 dl/g
Biocompatibility	ISO 10993	Biocompatible: Non-cytotoxic Non-irritating (intracutaneous and oral) Non-sensitive	Biocompatible: Non-cytotoxic Non-irritating (intracutaneous and oral) Non-sensitive
Sterility	ISO11135-1	SAL 10^{-6} (half cycle validation)	SAL 10^{-6} (rationale, identical blister pack and density)
EtO Residuals	ISO10993-7	< 2 mg/device	< 2 mg/device
Composition	In process verification	Conform Polyurethane specification	Conform Polyurethane specification additionally blended with with PEG20.000 and D&C Green
Package integrity	ISO11607	Qualified, Sterilized blisterpack	Qualified, Sterilized blisterpack
Shelf-life	ASTM F1980; Real time aging	18 months	6 months (interim results)

Table 1: Summary of bench testing

Summary of Substantial Equivalence

The design, materials, fundamental technology and intended use (safety and effectiveness) featured with the NASOPORE® FD Nasal Dressing are substantially equivalent to those featured with the following cleared device: Nasopore nasal dressing (K052099; Polyganics BV). The basis for equivalence is demonstrated by the comparisons in the following table:

	NASOPORE® FD (this submission)	**CURRENT NASOPORE® (K052099)**
Intended use	NASOPORE® is a fragmentable nasal dressing and is indicated for use in patients undergoing nasal/sinus surgery as a space occupying stent to separate and prevent adhesions between mucosal surfaces; to help control minimal bleeding following surgery or nasal trauma by tamponade effect and blood absorption.	NASOPORE® is a fragmentable nasal dressing and is indicated for use in patients undergoing nasal/sinus surgery as a space occupying stent to separate and prevent adhesions between mucosal surfaces; to help control minimal bleeding following surgery or nasal trauma by tamponade effect and blood absorption.
Materials	poly(urethane) blended with a color additive and PEG20.000	poly(urethane)
Design	Foam	Foam
Sizes	8cm	4 and 8 cm
Sterilization	EtO	EtO
Shelf-life	6 months (interim result)	18 months
Packaging	Single use, blister, aluminium pouch and silica gel, cardboard box	Single use, blister, cardboard box

Differences between the devices do not raise any significant issues of safety and effectiveness.