K052099

NOV 2 1 2005

510(k)
Summary of Safety and Effectiveness

Submitter:	Polyganics BV L.J. Zielstraweg 1 9713 GX, Groningen The Netherlands www.polyganics.com
Contact Person:	Jan Nieuwenhuis Managing Director Tel : +31 50 588 6588 Fax : +31 50 588 6599 Mobile : +31 653 211 303 E-mail : jan.nieuwenhuis@polyganics.com
Date Prepared:	July 27, 2005
General Provisions:	Trade Name: Nasopore® Common Name: Nasal Dressing Classification Name: Intranasal Splint, 21 CFR 874.4780 Device Classification: Class I
Predicate Devices:	- Seprapack/Sepragel; Genzyme; K012532 - Merogel™ nasal dressing; Xomed; K982731 - Meropack™ nasal dressing; Medtronic Xomed; K041381
Performance Standards	For the Nasopore performance, the FDA, under section 514 of the Food, Drug and Cosmetic Act, has not established standards.
Indications for 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.

Device Description

Nasopore is composed of a fragmentable 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 size and type are indicated on the label and are packed in a Tyvek pouch. Nasopore is indicated for single-use.

Performance Data:

The safety and effectiveness of the Nasopore Nasal Dressing have been demonstrated via data collected from design verification tests and analyses. The design verification testing consisted of the following:

- In vitro fragmentation testing
- Shelf life testing

Summary of Substantial Equivalence

The design, fundamental technology and intended use (safety and efficacy) featured with the Nasopore Nasal dressing are substantially equivalent to those featured with the competitor devices Seprapack/Sepragel (ref. 510(k)012532; Genzyme, Corp.), Merogel™ nasal dressing (ref. 510(k)982731, Xomed Surgical products, Inc) and Meropack™ nasal dressing (ref. 510(k)041381; Medtronic Xomed).

Biocompatibility, mechanical and physical property testing and in vitro fragmentation testing provide scientific evidence that Nasopore nasal dressing is substantially equivalent to the predicate devices. Evaluation of the Polyganics Nasopore® nasal dressing based on biocompatibility testing, clinical trial, and the comparison of the Nasopore nasal dressing with its predicate devices, shows that the Nasopore® is safe for use as a nasal dressing.

sopore® nasal dressing is substantially equivalent to the currently marketed predicate devices.

Device Characteristics of the Subject and Predicate devices

	Nasopore®	Sepra-pack/Sepragel	MeroGel™	MeroPack™
Company	Polyganics	Genzyme corporation	Xomed Surgical Products	Medtronic Xomed Inc.
510(k) Reference	This 510(k)	K012532	K982731	K041381
Device name	Intranasal Splint	Intranasal Splint	Intranasal Splint / non woven wound dressing	Intranasal Splint
Indications	Nasal/sinus surgery	Nasal/sinus surgery	Nasal/sinus surgery	Nasal/sinus surgery
Material composition	fragmentable poly(DL-lactide-co-ε-caprolactone) urethane	Chemically modified hyaluronic acid and carboxymethylcellulose	Esterified hyaluronic acid	Esterified hyaluronic acid and collagen
Method of action	Hygroscopic, fragments in contact with fluids	Hygroscopic, forms gelatinous mass in contact with fluids	Hygroscopic, forms gelatinous mass in contact with fluids	Hygroscopic, forms gelatinous mass in contact with fluids
Biocompatibility	ISO 10993	ISO 10993	ISO 10993	ISO 10993 and FDA guidance G95-1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 1 2005

Polyganics BV
c/o J.B. Hak, Ph.D.
Manager, Clinical and Regulatory Affairs
L.J. Zielstraweg 1
NL-9713-GX Groningen
The Netherlands

Re: K052099
Trade/Device Name: Polyganics Nasopore® nasal dressing
Regulation Number: 21 CFR 874.4780
Regulation Name: Intranasal splint
Regulatory Class: Class I
Product Code: LYA
Dated: November 7, 2005
Received: November 9, 2005

Dear Mr. Hak:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number: K052099

Device Name: **Nasopore® nasal dressing**

Indications for Use:

Nasopore® nasal dressing 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)

(Optional Format 1-2-96)

(Division Sign-Off)

510(k) Number K052099

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

510(k) Number K052099