510(k)
Summary of Safety and Effectiveness

Submitter:

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MAY - 7 2007

Contact Person:

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Date Prepared: March 07, 2007

General Provisions:

Trade Name: Nasopore®

Common Name: Fragmentable ear dressing

Classification Name: ENT synthetic polymer material
21 CFR 874.3620, Class II

Predicate Devices:

- Invotec Ear Tampon (Wick) w/String; Invotec Internat.; K973578
- Nasopore® nasal dressing, Polyganics, K052099

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® Ear is a fragmentable ear packing and is indicated for use in patients, undergoing ear surgery, as a space occupying stent to separate and prevent adhesions between mucosal surfaces; to help control minimal bleeding, following ear surgery, by tamponade effect and blood absorption.

Device Description

Nasopore® Ear is composed of a bioresorbable poly(DL-lactide-co-ε-caprolactone) urethane that fragments within several days after insertion in the outer and / or middle ear, whereafter it will fall out of the ear or leaves the body by the natural mucus flow.

The type of Nasopore® Ear is indicated on the label. Nasopore® Ear is packed in a blister closed by a medical paper lid. Nasopore® Ear is indicated for single-use.

Performance Data:

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

- In vitro degradation testing
- Shelf life testing

Summary of Substantial Equivalence

The intended use of Nasopore Ear is substantially equivalent to those featured with the competitor device Invotec Ear Tampon (Wick) w/String (ref. 510(k)973578). The safety (biocompatibility) and efficacy of Nasopore® Ear is demonstrated by its substantial equivalent Nasopore® Nasal dressing (ref. 510(k)052099; Polyganics BV).

Polyganics BV already markets Nasopore® Nasal Dressing. The subject device, Nasopore® Ear, is made from the same material as Nasopore® Nasal Dressing. The subject device is substantially equivalent to Nasopore® Nasal Dressing with respect to physical characteristics and with regard to the intended use of the device, i.e. a space occupying stent to separate and prevent adhesions between mucosal surfaces and help control minimal bleeding following surgery, by tamponade effect and blood absorption, Nasopore® Nasal dressing in the nasal/sinus cavities and Nasopore® Ear in the outer ear. The predicate device Nasopore® Nasal Dressing is made of a fragmentable poly(DL-lactide-co-ε-caprolactone) urethane and the identical manufacturing process is used to produce the foam. The subject and predicate device are made of poly(DL-lactide-co-ε-caprolactone) urethanen, which has demonstrated to be satisfactory biocompatible. Next to the Nasopore® nasal dressing, Polyganics also markets Nasopore® Ear (K062540). This product is intended as a packing used after outer ear surgery. However the middle ear possesses a connection to the Eustachian tube, which indicates that the fragments, obtained during fragmentation, can leave the body via the natural mucus flow.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Polyganics BV
c/o Jan Nieuwenhuis
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NL-9713-GX Groningen
The Netherlands

MAY - 7 2007

Re: K070715
Trade/Device Name: Polyganics Nasopore® Ear
Regulation Number: 21 CFR 874.3620
Regulation Name: ENT Synthetic Polymer Material
Regulatory Class: II
Product Code: NHB
Dated: March 12, 2007
Received: March 14, 2007

Dear Ms. Nieuwenhuis:

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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M B Eydelman, MD

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

K070715

Indications for Use Form

510(k) Number: K070715

Device Name: **Nasopore® Ear**

Indications for Use:

Nasopore® Ear is a fragmentable ear packing and is indicated for use in patients, undergoing ear surgery, as a space occupying stent to separate and prevent adhesions between mucosal surfaces; to help control minimal bleeding, following ear surgery, 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 _____

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

510(k) Number K070715