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K98 1374

POREX SURGICAL INC.

4715 Roosevelt Highway, College Park, Georgia 30349 USA
(770) 969-8145 • (800) 521-7321 • Fax: (770) 969-8045

510(k) SUMMARY

Manufacturer and Submitter

Porex Surgical, Inc.
4715 Roosevelt Highway
College Park, GA 30349

Tel: (770) 969-8145
Fax: (770) 969-8045

Contact: Howard Mercer, Ph.D.

Date: May 30, 1997

Trade Name: Porex Nostril Retainer
Classification Name: Nasal Conformer - Class II Device

Substantially equivalent to:
A) Nasal Retainer manufactured by Silimed Inc.

Device description:

A nasal retainer is used after aesthetic and reconstructive rhinoplasty, after rhinoseptoplasty, after rhinoseptocheiloplasty, and/or primary and secondary rhinocheiloplasty to assist in keeping the nasal passages open and reduce swelling. It is a silicone U shaped with the legs of the U being tubes that are inserted into the nostrils.

The device of this submission is the predicate device and is identical to the predicate device, in all aspects except for method of sterilization and labeling

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Howard A. Mercer, Ph.D.
Regulatory Affairs
Porex Surgical Inc.
415 Roosevelt Highway
College Park, GA 30349

Re: K981374
Porex Nostril Retainers
Dated: April 15, 1998
Received: April 16, 1998
Regulatory class: Unclassified
Procode: 77 LYA

Dear Dr. Mercer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

William Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

POREX SURGICAL INC.
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510(k) Number : K981374

Device Name: Nostril Retainer

Indications for Use:

The Porex Nostril Retainer is designed for use after aesthetic and reconstructive rhinoplasty, after rhinoseptoplasty, after rhinoseptocheiloplasty, and/or primary and secondary rhinocheiloplasty.

(PLEASE DO NOT WRITE BELOW THIS LINE)

Prescription Use: ✓ OR Over the Counter Use: _____
(Per 21CFR801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K981374