JUN 10 2014

K132920

510(k) Summary (21 CFR § 807.92(c))

Submitter:	Spirox, Inc. 3475-0 Edison Way Menlo Park, CA 94025
Contact:	Mike Rosenthal Vice President, Research & Development, Spirox Phone: 650.503.3329 Fax: 650.741.0029 Email: mrosenthal@d3dc.com
Date Summary Prepared:	03 June 2014
Device Trade Name:	Spirox INEX Device
Common Name:	Ear, nose and throat synthetic polymer material
Classification Name:	Polymer, Ear, Nose and Throat, Synthetic, Absorbable (21 CFR §874.3620)
Product Code:	NHB
Equivalent Devices:	Ethicon's PDS Flexible Plate (K092590 - 17 Feb 2010) MacroPore's ENT Reconstruction Film (K012769 - 25 Oct 2001) Synthes' Resorbable Fixation Systems (K021928 - 09 Jan 03) Synthes' Rapid Resorbable Fixation Systems (K062789 27 Feb 2007) Porex Surgical MedPor Customized Surgical Implant (K083621 Feb 2009)

Device Description:

The Spirox INEX implantable sheet is an absorbable device comprised of a poly (L-lactide-co-D,L-lactide) 70:30. The product is provided as a perforated sheet comprised of multiple "rod" like elements. The sheet is nominally 24.5 x 20.0 mm with a thickness of 1.1 mm. The bridge sections are nominally 3.0 x 1.9 mm and the voids are nominally 2.4 x 1.9 mm. The implant can be trimmed and shaped to dimensions suitable for the surgical need. The device is implanted using standard surgical tools and techniques The Spirox INEX implantable sheet is a sterile, single use device.

Intended Use / Indications for Use:

The Spirox INEX absorbable implant is indicated for supporting nasal septal cartilage.

Technological Characteristics & Substantial Equivalence:

The Spirox INEX Device is substantially equivalent to Ethicon's PDS Flexible Plate cleared under K092590 (17 February 2010), MacroPore's ENT Reconstruction Film cleared under K012769 (25 October 2001), Synthes' Resorbable Fixation Systems cleared under K021928 and K062789 (09 January 2003 and 27 February 2007) and Porex's MedPor Customized Surgical Implant (03 February 2009). The intended use of the Spirox INEX Device is consistent with a more limited intended use cleared as compared to the above referenced predicate devices. The Spirox INEX device is indicated for use in procedures requiring nasal cartilage support only. Both the subject and predicate devices share similar technological characteristics, in that, all devices are long-term or permanent implants that employ the use of absorbable or nonabsorbable polymers and are formed, shaped and placed using standard surgical instruments and tools.

Non-Clinical Performance Data:

Design verification testing confirmed that the Spirox INEX Device performs according to the product specifications. Device evaluation consisted of mechanical and functional testing performed pursuant to Spirox' design / system verification protocol; comparative testing with the cited predicate devices and human factors / usability assessments. Additionally, the device safety, biocompatibility and use was verified in a GLP animal study. Biocompatibility testing was conducted according to ISO 10993 "Biological Evaluation of Medical Devices" and FDA's recent guidance. The sterilization validation complies with the requirements prescribed in ISO 11137 for radiation sterilization. Packaging and shipping validation studies were conducted pursuant to the applicable ISO and ISTA 3A guidelines.

Summary:

Based on the product technical information, intended use / indications for use and non-clinical performance data provided in this premarket notification, the Spirox INEX Device has been shown to be substantially equivalent to the currently marketed predicate devices. Test data included in this 510(k) submission demonstrate similar performance of the Spirox INEX device as compared to the predicate devices. The differences between the subject and predicate devices do not raise new types of safety or effectiveness questions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

June 10, 2014

Spirox, Inc.
c/o Mr. Michael Rosenthal
Vice President of Research & Development
3475-0 Edison Way
Menlo Park, CA 94025

Re: K132920
Trade/Device Name: Spirox Inex Device
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, Nose and Throat Synthetic Polymer Material
Regulatory Class: Class II
Product Code: NHB
Dated: May 8, 2014
Received: May 9, 2014

Dear Mr. Rosenthal:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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

K132920

Indications for Use Statement

510(k) Number if Known: K132920

Device Name: Spirox INEX Device

Indications for Use:

The Spirox INEX absorbable implant is indicated for supporting nasal septal cartilage.

Prescription Use ☒ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

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

Concurrent of CDRH, Office of Device Evaluation (ODE)

Vasant G.
Malshet -S