



Food and Drug Administration
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December 4, 2015

Spirox, Inc.
Mr. Mike Rosenthal
Chief Operating Officer
3475-0 Edison Way
Menlo Park, CA 94025

Re: K152958
Trade/Device Name: Inex Absorbable Nasal Implant
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, Nose, And Throat Synthetic Polymer
Regulatory Class: Class II
Product Code: NHB
Dated: October 5, 2015
Received: October 7, 2015

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 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" (21 CFR 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

510(k) Number (if known)

K152958

Device Name

INEX Absorbable Nasal Implant

Indications for Use (Describe)

The Spirox INEX Absorbable Nasal Implant is indicated for supporting nasal upper and lower cartilage.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 6: 510(k) Summary (21 CFR § 807.92(c))

I: SUBMITTER INFORMATION

Submitter: Spirox, Inc.
3475-0 Edison Way
Menlo Park, CA 94025

Contact: Mike Rosenthal
Chief Operating Officer, Spirox, Inc.
Phone: 650.503.3329
Fax: 650.618.1440
Email: mrosenthal@spiroxmed.com

Date Summary Prepared: 01 October 2015

II: SUBJECT DEVICE INFORMATION

Device Trade Name: INEX Absorbable Nasal Implant
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

III: PREDICATE DEVICE INFORMATION

Predicate Device: INEX Absorbable Sheet (K132920)

No recalls, market withdrawals or safety alerts were identified in FDA's database for the above referenced predicate device.

No reference devices were used in this submission.

IV: DEVICE DESCRIPTION:

The Spirox INEX Absorbable Nasal Implant System is intended to support cartilage in the nasal lateral wall. The System consists of the INEX Absorbable Nasal Implant and accessory Delivery Tool. The implant is composed of a PLLA-PDLA copolymer that is predominantly cylindrical in shape with an approximate diameter of 1mm and an overall length of 24mm. The distal end of the implant is forked to facilitate anchoring during implantation and the proximal end is narrower for increased flexibility. The disposable Delivery Tool is comprised of a non-patient contacting handle assembly and a medical grade stainless steel 16 gauge delivery cannula. The Delivery Tool enables placement of the implant in a minimally invasive manner. The INEX Absorbable Nasal Implant and accessory Delivery Tool are provided sterile and are intended for single-use only.

V. INDICATIONS FOR USE:

The Spirox INEX Absorbable Nasal Implant is indicated for supporting nasal upper and lower lateral cartilage.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

The primary technological principle for the subject and predicate devices is to provide nasal cartilage support. The subject and predicate devices accomplish this function by similar means. At a high level, the subject and predicate devices are based on the following same technological characteristics:

- The devices both employ the use of the same PLLA/PDLA copolymer raw material.
- The devices are sterilized via gamma irradiation pursuant to the applicable ISO standard and both devices have equivalent surface finishes.
- The devices were designed to have stiffness that is comparable to nasal cartilage.

The following technological differences exist between the subject and predicate devices:

- The subject device is provided in a single “rod” configuration designed for lateral cartilage support. The predicate device for septal cartilage support is provided in a sheet configuration that is comprised of eight (8) “rod” subsets.
- The subject device can be implanted with an accessory Delivery Tool or off-the shelf surgical tools. The predicate device is implanted with off-the shelf surgical tools.

VII. PERFORMANCE DATA:

The following performance data were provided in support of the substantial equivalence determination.

Bench Testing

Verification tests for the INEX Absorbable Implant included: a) Dimensional Inspections; b) Implant Migration; c) Flexural Rigidity; d) Bend Radius; and, e) Degradation Testing. Verification tests for the accessory Delivery Tool included: 1) Dimensional Inspections; 2) Plunger Force Verification; 3) System Functionality Verification; 4) Handle Joint Strength Verification; 5) Cannula Joint Strength Verification; and, 6) Plunger Bond Verification. These tests were conducted on gamma and e-beam sterilized devices at baseline and on devices aged to six (6) months. Passing results were obtained for all design verification tests.

Biocompatibility Testing

Biocompatibility tests were conducted in accordance with the standard recognized by FDA (AAMI/ANSI/ISO 10993-1) “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing” and FDA’s applicable guidance document (“Use of International Standard ISO 10993”, draft document issued on 24 April 2013). Both the subject and predicate INEX devices are categorized as “tissue/bone” implant devices with a “permanent” duration of contact (>30 days). As such, the following tests were conducted pursuant to the standard and the Agency’s guidance: 1) Cytotoxicity; 2) Sensitization; 3) Irritation; 4) Systemic Toxicity; 5) Genotoxicity; and, 6) Implantation. Biocompatibility testing was conducted on the predicate device and leveraged for the subject device. The justification for leveraging such test results included the following rationale: 1) both devices are comprised of the same raw material provided by the same vendor; and, 2) both devices are manufactured by the same contract manufacturer using the same manufacturing processes. The accessory Delivery Tool 304 Stainless Steel

cannula is the only patient contacting portion of the accessory tool. Testing was conducted based on categorization of this portion of the Delivery Tool as a “surface” device in contact with “breached or compromised surfaces” with a “limited” duration of contact (≤ 24 hours). The patient contacting portion described above was subjected to cytotoxicity testing with acceptable results. No further biocompatibility tests were conducted because the subject material has a long history of use in medical devices, is exceptionally well characterized and has demonstrated adequate biocompatibility for a wide variety of intended uses, including “tissue/bone contacting” (< 24 hours) devices, and “skin/breached surface contacting” devices (e.g. scalpels, retractors).

Sterilization Data

The gamma radiation sterilization parameters for the INEX Absorbable Nasal Implant Device comply with the requirements prescribed in the applicable standards ISO 11137-1:2006 “Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices”, and ISO 11137-2:2006 “Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose”. The validation results support an SAL of 10^{-6} . Sterilization validation for the accessory Delivery Tool using e-beam radiation was also validated per the same standard and supported a minimum radiation dose of 25kGy and a SAL of 10^{-6} .

Packaging and Shipping Validation

Packaging and shipping validation studies were successfully conducted on the predicate INEX Implantable Sheet pursuant to the applicable ASTM guidelines. These tests included seal peel, bubble emission and dye migration tests per ASTM F88 “Standard Test Method for Seal Strength of Flexible Barrier Materials”; ASTM F2096 “Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)”; ASTM F1929 “Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration”; and ISO 11607-1 “Packaging Materials and Systems for Medical Devices which are to be Sterilized – Part 1: General Requirements and Test Methods”. All tests results met the acceptance criteria demonstrating that the packaging process and the packaging materials maintained their integrity throughout the shelf-life. Additionally, the ISTA 3A standard was used to evaluate package performance under simulated transport conditions. All tests results met the acceptance criteria. An equivalency analysis between the subject and predicate implant devices confirm the applicability of the completed verification tests for the predicate device to the subject device. Comparable packaging and shipping validation testing was completed for the accessory Delivery Tool. Such test results along with performance data on aged product also support the specified shelf-life for the accessory Delivery Tool.

Clinical Performance Data

Clinical testing of the INEX Absorbable Nasal Implant device and accessory Delivery Tool included a study of thirty (30) subjects. The study was conducted at three (3) investigational sites in Germany. The study was a prospective, multi-center, non-randomized, single arm study of which thirty (30), 29, 22 and 10 subjects were available for safety and effectiveness analysis at one (1), 3, 6 and 12 months respectively. The device was used to support upper and lower lateral nasal cartilage in subjects with nasal valve collapse due to weakened lateral cartilage. A total of 56 implants were placed in 30 subjects (26 bilateral and 4 unilateral placements).

Primary Safety Endpoint

The three (3) month safety results meet the criteria outlined for the primary safety endpoint for this study. Specifically, this endpoint is met because there were five (5) implant/device related events reported in four (4) subjects. Such events included hematoma (1); inflammation (1); and extrusions (3). A per subject device related adverse event rate of 13% is comparable to the adverse event rate reported in published studies where other alloplastic materials are used in accordance with their commercial labeling to provide lateral cartilage support in similar study populations. Additionally, the types of reported adverse events are expected and comparable to those reported for other long-term absorbable implants. The three (3) extrusions reported in the Spirox study were internal nasal cavity extrusions related to implantation technique or patient nasal manipulation. None of these events were associated with any signs of tissue rejection or adverse foreign body response and all occurred within the first post-operative month. The implant devices were easily removed with tweezers at the time of observation requiring no surgical intervention and resolved with no clinical sequelae.

Primary Efficacy

Performance and effectiveness criteria were met based on subjects showing a mean NOSE Score reduction of 64.8% (n=30) through the one (1) month follow-up, 63.4% (n=29) through the three (3) month follow-up period and 56.4% (N=22) through the six (6) month follow-up period. NOSE Score reductions were comparable to those reported in published literature for more invasive and extensive surgical procedures for nasal obstruction. Additionally, external and internal physical exam findings were normal and showed no evidence of implant migration. Finally, the results from an independent physician review of the collected photographs showed that of the thirty (30) subjects one (1) showed an adverse cosmetic effect at a three (3) month follow-up visit which was resolved or not observed at the six (6) month time point.

Summary

The results from the above described clinical study demonstrate the safety and effectiveness of the INEX Absorbable Nasal Implant and its ability to support nasal upper and lower lateral cartilage.

VIII CONCLUSIONS:

Based on the intended use, technological characteristics, bench and clinical performance data provided in this premarket notification, the INEX Absorbable Nasal Implant Device has a safety and effectiveness profile that is substantially equivalent to the predicate device. The information included in this 510(k) submission demonstrates the same intended use, similar indications for use and technological characteristics of the INEX Nasal Implant Device as compared to the predicate device. The differences between the subject and predicate devices do not raise different types of safety or effectiveness questions and the performance data demonstrate substantial equivalence.