DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 23, 2016

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

Re: K161191
Trade/Device Name: Latera Absorbable Nasal Implant
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, Nose, And Throat Synthetic Polymer Material
Regulatory Class: Class II
Product Code: NHB
Dated: May 27, 2016
Received: May 31, 2016

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161191

Device Name
Latera Absorbable Nasal Implant

Indications for Use *(Describe)*
The Spirox Latera Absorbable Nasal Implant is indicated for supporting nasal upper and lower lateral 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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K161191: Special 510(k) Summay

I: SUBMITTER INFORMATION

Submitter: Spirox, Inc.
3475-O 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: 26 April 2016

II: SUBJECT DEVICE INFORMATION

Device Trade Name: Latera 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 Nasal Implant (K152958)

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 Latera Absorbable Nasal Implant System is intended to support cartilage in the nasal lateral wall. The System consists of the Latera Absorbable Nasal Implant (Implant) and Accessory Delivery Device (Delivery Device). The Implant is composed of a PLLA-PDLA copolymer that is predominantly cylindrical in shape with an approximate diameter of 1mm and 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 Device is comprised of a non-patient contacting handle assembly and a medical grade stainless steel 16 gauge delivery cannula. The Delivery Device enables placement of the Implant in a minimally invasive manner. The Latera Absorbable Nasal Implant and Accessory Delivery Device are provided sterile and are intended for single-use only.

V. INDICATIONS FOR USE

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

VI. MODIFICATIONS OF SUBJECT DEVICE

The INEX Absorbable Nasal Implant, which includes the INEX Absorbable Nasal Implant (Implant) and Accessory Delivery Tool (Delivery Tool), was cleared on December 4, 2015 (K152958). The cleared device has been modified to include changes to device packaging and enhance usability aspects of the system. Importantly, the modified device, the Latera Absorbable Nasal Implant and Accessory Delivery Device, has the same fundamental scientific technology and intended use/indications for use as the cleared predicate device. The following characteristics remain unchanged between the modified and predicate device:

- No modifications are being made to the Implant device itself; the Implant retains the same dimensional and material attributes previously described under K152958.
- No changes are being made to the sterilization methods; the Implant is sterilized via gamma irradiation and the Delivery Device is sterilized via e-beam irradiation pursuant to the applicable ISO standards previously described under K152958.
- No modifications are being made to the shelf-life; both the Implant and the Delivery Device will retain the same shelf-life previously described under K152598.

The proposed modifications to the subject device include:

- The addition of a silicone coating to the cannula portion of the Delivery Device.
- The addition of a positioning guide “Implant Positioning Guide” to facilitate pre-procedure planning including external visualization of the internal target implant site.
- The inclusion of more prominent Implant orientation features on the Delivery Device handle distal end.
- Changes to the Implant packaging to accommodate an implant tray to facilitate implant handling and further protect the implant during shipping.
- Changes to the Delivery Device packaging to accommodate modifications to handle shape, inclusion of the Implant Positioning Guide.

VII. DESIGN CONTROL ACTIVITIES

The risk analysis method used to assess the impact of the modifications was a Failure Mode and Effects Analysis (FMEA). The verification and validations tests that were performed as a result of this risk analysis assessment included: 1) Verification Testing; 2) Sterilization Validation; 3) Packaging and Shelf-Life Testing; 4) Transit Testing; 5) Biocompatibility Testing; and 6) Human Factors/Usability Testing. The methods used for the verification and validation tests for the modified device are the same as those submitted in the original 510(k) application for the predicate device.

VIII CONCLUSION

Based on the same intended use / indications for use and fundamental scientific technology, the modified Latera Absorbable Nasal Implant Device has a safety and effectiveness profile that is substantially equivalent to the predicate device.