August 17, 2023

Spirair, Inc.
Tracey Henry
Regulatory Consultant
6084 Monterey Hwy, 108
San Jose, California 95138

Re: K223167
Trade/Device Name: Spirair Nasal Septal Strap
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, Nose, And Throat Synthetic Polymer Material
Regulatory Class: Class II
Product Code: NHB
Dated: July 17, 2023
Received: July 17, 2023

Dear Tracey Henry:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joyce C. Lin -S

for Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223167

Device Name
Spirair Nasal Septal Strap

Indications for Use *(Describe)*
The Spirair Nasal Septal Strap is used to support and straighten minor deviations in septal cartilage when sufficient healthy cartilage exists, and the cartilage is appropriately mobilized utilizing standard septoplasty techniques.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

I. SUBMITTER

Spirair, Inc.
6084 Monterey Hwy, #108
San Jose, CA 95138
Phone: (844) 434-9673

Contact Person: James Kintzing, CEO
Date Prepared: August 15, 2023

II. DEVICE

Name of Device:	Spirair Nasal Septal Strap
Common or Usual Name:	Ear, Nose, Throat Synthetic Polymer Material
Classification Name:	Polymer, Ear, Nose and Throat, Synthetic, Absorbable
Regulatory Class:	Class II
Product Code:	NHB
Regulation Number:	21 CFR 874.3620

III. PREDICATE/REFERENCE DEVICE

Predicate Device:	Spirox INEX Implantable Sheet (K132920)
Reference Device:	Stratafix™ Symmetric PDS™ Plus, Knotless Tissue Control, (K141776)

IV. DEVICE DESCRIPTION

The Spirair Nasal Septal Strap is a bioabsorbable, polydioxanone ribbon that is intended to be used in nasal surgery. The Nasal Septal Strap is 190 mm long and 0.65 mm thick with barbed features (“anchors”) which enable attachment to and support of nasal septal cartilage. The Nasal Septal Strap is trimmed to size by the physician to suit the anatomical conditions and clinical use case. The device includes a surgical needle to enable attachment to the tissue which is trimmed off after use. The Nasal Septal Strap is provided sterile as a single use device and when permanently implanted, is resorbed within a 6-month period.

V. INDICATIONS FOR USE

The Spirair Nasal Septal Strap is used to support and straighten minor deviations in septal cartilage when sufficient healthy cartilage exists, and the cartilage is appropriately mobilized utilizing standard septoplasty techniques.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Nasal Septal Strap (subject device) has the same intended use and fundamental technology as the predicate device, Spirox INEX Implantable Sheet.

The subject device shares similar technological characteristics with the predicate device (i.e., principle of operation, mechanical properties, bioabsorbable material, biocompatibility, sterility). Like the predicate device, the subject device can be trimmed to size and implanted using standard surgical tools and techniques.

The subject device also includes features that enable surgical implantation without the use of off-the-shelf sutures required for the predicate. These features are equivalent to the surgical tools used to implant the predicate device and therefore do not introduce any different questions of safety or effectiveness. These features are also similar to the design of the reference device, Stratafix™ Symmetric PDS™ Plus, Knotless Tissue Control, and were tested using similar testing methodologies as the reference device in support of substantial equivalence.

VII. PERFORMANCE DATA

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

Performance Testing	**Data provided**
Biocompatibility Testing	The biocompatibility evaluation for the Nasal Septal Strap was conducted in accordance with *ISO 10993-1, Biological Evaluation of medical devices – Part 1: Evaluation and testing within a risk management process (2018)* and FDA Guidance: *Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*, *September 4, 2020.* This evaluation determined that the materials in the Nasal Septal Strap do not pose a risk of negative interaction with patients. The implantable portion of the Nasal Septal Strap was assessed as a Permanent Implant (>30 Day) whereas the surgical needle was tissue contacting with Limited (<24 hour) duration. The following tests were performed: • Cytotoxicity • Sensitization • Irritation • Implantation • Chemical characterization
Distribution, Packaging and Shelf-Life Testing	Distribution testing and Accelerated Aging of the Nasal Septal Strap was successfully completed. Final packaging and device performance were successfully tested demonstrating integrity of the sterile barrier and preservation of the Nasal Septal Strap properties for the labeled shelf-life.

Performance Testing	Data provided
Performance Testing – Bench	Design verification testing was performed on the Nasal Septal Strap and demonstrated that the physical and functional requirements were met. Specifically, the following was tested: • Mechanical properties • Material properties • Migration of implant • *In vitro* degradation
Performance Testing – Animal	*In vivo* implantation was performed in an GLP animal study and demonstrated device safety, degradation, and biocompatibility performance of the device.
Performance Testing – Clinical	Safety data from a clinical study was included to support the *in vivo* implantation of the Nasal Septal Strap in septal nasal cartilage. These data were collected as part of a prospective, multi-center, multi-cohort, early feasibility study from one US site. Limited interim data was available out to six months and demonstrated that the Nasal Septal Strap was safe for implantation in nasal septal cartilage through the resorption period. There were no adverse device effects reported. There was (1) procedure-related event reported in one (1) subject; adverse event was not unanticipated and reported in traditional septoplasty procedures.

VIII. CONCLUSIONS

In conclusion, the intended use is the same as that of the predicate device. Performance testing shows that any differences in indications for use, and technological characteristics from the predicate device do not affect safety and effectiveness, and demonstrates that the subject device is substantially equivalent to the predicate device.