March 22, 2024

Spirair, Inc.
Tracey Henry
Regulatory Consultant
415 Grand Avenue
Suite 201
San Francisco, California 94080

Re: K233569
Trade/Device Name: SeptAlign
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, Nose, And Throat Synthetic Polymer Material
Regulatory Class: Class II
Product Code: NHB
Dated: February 27, 2024
Received: February 27, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Shuchen Peng -S

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)*
K233569

Device Name
SeptAlign

Indications for Use *(Describe)*
SeptAlign 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.

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510(k) Summary

I. SUBMITTER

Spirair, Inc.
415 Grand Avenue, Suite 201
San Francisco, CA 94080
Phone: (844) 434-9673

Contact Person: James Kintzing, CEO
Date Prepared: November 6, 2023

II. DEVICE

Name of Device:	SeptAlign
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:	Spirair Nasal Septal Strap (K223167)
Reference Device:	Spirox INEX Absorbable Nasal Implant (K152958)

IV. DEVICE DESCRIPTION

The Spirair SeptAlign implant is a bioabsorbable, polydioxanone ribbon that is intended to be used in nasal surgery. SeptAlign is 190 mm long and 0.65 mm thick with barbed features ("anchors") which enable attachment to and support of nasal septal cartilage. SeptAlign 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. SeptAlignis provided sterile as a single use device and when permanently implanted, is resorbed within a 6-month period.

The SeptAlign implantis provided preloaded into a disposable delivery tool comprised of a non-patient contacting handle assembly and a medical grade stainless steel delivery cannula and trocar. The delivery tool enables placement of the distal portion of the implant in a minimally invasive manner. The SeptAlign implant and accessory delivery tool are provided sterile and are intended for single-use only.

V. INDICATIONS FOR USE

SeptAlign 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 primary technological principle for the subject and predicate devices is to support and straighten minor deviations in healthy septal cartilage during septoplasty procedures. There has been no change to the implantable portion of the subject device, thus the subject device has the same principle of operation, mechanical properties, bioabsorbable material, biocompatibility, sterility and performance characteristics as the predicate device.
The subject device differs from the predicate device in that it can be implanted with an accessory delivery tool in addition to off-the-shelf surgical tools. This feature is similar to the reference device, Spirox INEX Absorbable Nasal Implant (K152958) and performance testing was successfully completed 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 SeptAlign 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 8, 2023.* This evaluation determined that the materials in the Nasal Septal Strap and accessory delivery tool do not pose a risk of negative interaction with patients. The implantable portion of SeptAlign was assessed as a Permanent Implant (>30 Day). The surgical needle and patient contacting components of the delivery tool were assessed as Externally Communicating: Tissue/bone/dentin 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 SeptAlign with delivery tool was successfully completed.

Performance Testing	Data provided
	Final packaging and device performance were successfully tested demonstrating integrity of the sterile barrier and preservation of SeptAlign performance for the labeled shelf-life.
Performance Testing – Bench	Design verification testing was performed on SeptAlign with delivery tool and demonstrated that the physical and functional requirements were met. Specifically, the following tests were performed on the accessory delivery tool: • Deployment/ Simulated Use functionality • Mechanical integrity of handle and deployment mechanism • Cannula Joint Strength

No animal or clinical performance testing was required to support substantial equivalence.

VIII. CONCLUSIONS

In conclusion, the intended use and indications for use are the same as that of the predicate device. Performance testing shows that use of the accessory delivery tool does not affect safety and effectiveness, and demonstrates that the subject device is substantially equivalent to the predicate device.