July 30, 2026

Spirair, Inc.
Tracey Henry
VP Clinical, Regulatory, Quality
415 Grand Ave.
Suite 201
South San Francisco, Ca 94080

Re: K260620
Trade/Device Name: SeptAlign (SPLN001)
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, Nose, And Throat Synthetic Polymer Material
Regulatory Class: Class II
Product Code: NHB
Dated: June 30, 2026
Received: June 30, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260620

Please provide the device trade name(s).

SeptAlign (SPLN001)

Please provide your Indications for Use below.

SeptAlign is used to support and straighten deviations in septal cartilage when sufficient healthy cartilage exists, and the cartilage is appropriately mobilized utilizing standard septoplasty techniques.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

I. SUBMITTER

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

Contact Person: Tracey Henry
Date Prepared: July 29, 2026

II. DEVICE

Name of Device:	SeptAlign (SPLN001)
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: SeptAlign (K251790)

IV. DEVICE DESCRIPTION

SeptAlign consists of a bioabsorbable implant and single use delivery device. The polydioxanone implant is 100 mm long and 0.65 mm thick with bi-directional anchors which enable mechanical correction of cartilaginous nasal septal deviations without cartilage resection. The implant also includes a surgical (implant) needle to enable placement which is trimmed off after use. The implant supports the cartilage in the straightened positioned as the cartilage remodels and is fully resorbed within a 6-month period.

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

V. INDICATIONS FOR USE

SeptAlign is used to support and straighten 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 subject and predicate device share the same technological characteristics. Both devices utilize a bioabsorbable polydioxanone implant to support and straighten septal cartilage via bi-directional anchors which are secured through the septum, distal and proximal to the deviation. The implant in both devices applies mechanical traction to the straightened cartilage throughout the cartilage remodeling process and is resorbed within six months. Both devices utilize a single-use delivery tool for placement of the distal anchor portion of the implant in the septum. The proximal end of the implant is placed with an implant needle for both devices, which is trimmed off along with any excess implant material.

The subject device differs from the predicate device with respect to changes in the geometry of the implant features (shorter implant with wider anchors positioned closer together). The subject device delivery tool was also updated to improve the ease of use, specifically with regard to deploying the implant and securing the distal anchor. The subject device also includes two new features, a Depth Indicator attached to the trocannula which provides tactile physician feedback when puncturing the cartilage, and an actuator lock which prevents inadvertent deployment of the implant.

The subject device also includes new packaging designed to simplify presentation of the sterile product to the user.

Characteristic	SeptAlign (Subject Device)	SeptAlign (Predicate Device)	Comparison
Intended Use/ Indications for Use	SeptAlign is used to support and straighten deviations in septal cartilage when sufficient healthy cartilage exists, and the cartilage is appropriately mobilized utilizing standard septoplasty techniques.	SeptAlign is used to support and straighten deviations in septal cartilage when sufficient healthy cartilage exists, and the cartilage is appropriately mobilized utilizing standard septoplasty techniques.	Same
Target Population	Adults	Adults	Same
Anatomical site	Nasal passageway: nasal septal cartilage	Nasal passageway: nasal septal cartilage	Same
Intended Users	Prescription only. Qualified medical personnel (physicians)	Prescription only. Qualified medical personnel (physicians)	Same
Clinical Setting	Surgical setting	Surgical setting	Same
Implant Design	Length: 100mm Body Thickness/Width: 0.65mm Bidirectional Anchors 6.9mm (distal) and 1.9mm(proximal)	Length: 190mm Body Thickness/Width: 0.65mm Bidirectional Anchors 2.5mm (distal) and 2.0mm (proximal)	Shorter implant body with larger distal anchor and closer together proximal anchors

Characteristic	SeptAlign (Subject Device)	SeptAlign (Predicate Device)	Comparison
	Proximal anchor chain: 25.5mm (18 anchors) Implant can be trimmed to dimensions suitable for surgical need.	Proximal anchor chain: 69.5mm (22 anchors) Implant can be trimmed to dimensions suitable for surgical need.	
Patient Contacting Materials	Poly(dioxanone) Stainless Steel Acrylonitrile Butadiene Styrene (ABS) Polyvinyl Chloride Plastisol (PVC)	Poly(dioxanone) Stainless Steel	Addition of ABS component and PVC tip protector.
Resorption	6 months	6 months	Same
Implant Properties	Tensile strength/distal anchor strength > 3lbs Proximal anchor strength > 1.5lbs	Tensile strength/distal anchor strength > 3lbs Proximal anchor strength > 1.5lbs	Same
Single patient use?	Yes	Yes	Same
Sterilization	EtO	EtO	Same
Packaging	Tyvek with integrated foil pouch	Tyvek sealed in foil pouch	Same
Shelf-Life	6 months	6 months	Same
Compatibility with environment/other devices	Labeling specifies "Do not expose the device to high temperatures such as those generated by electro-surgical instruments."	Labeling specifies "Do not expose the device to high temperatures such as those generated by electro-surgical instruments."	Same

VII. PERFORMANCE DATA

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

Performance Testing	Data provided
Biocompatibility Testing	A biocompatibility evaluation for the modified device 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, 2023.* This evaluation determined that the materials in the modified device do not pose a risk of negative interaction with patients.

Performance Testing	Data provided
Sterilization	Sterilization testing was successfully completed in accordance with ISO 11135-1:2014 and demonstrated an SAL of 10^{-6}. Bacterial endotoxins test (BET), a.k.a. Limulus amebocyte lysate (LAL) testing was conducted per current test guidelines: *USP <85> Bacterial Endotoxin Test* and *AAMI ST72 Bacterial endotoxins- test methodologies, routine monitoring and alternatives to batch testing* and confirmed that the device meets established pyrogen limit specifications.
Distribution, Packaging and Shelf-Life Testing	Distribution testing and Accelerated Aging for the updated packaging was successfully completed. 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 and validation testing was performed and demonstrated that performance and safety requirements were met and the device performed as intended. Specifically, the following tests were performed to verify the design changes since the predicate: • Implant performance and integrity • Mechanical integrity of delivery tool • Physician usability testing in a clinically relevant model • Deployment/ Simulated Use functionality

No animal performance testing 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 demonstrates that the modified SeptAlign device design does not affect safety and effectiveness, and the subject device is substantially equivalent to the predicate device.