January 16, 2026

Spirair, Inc
Tracey Henry
VP Clinical Affairs, Regulatory and Quality
415 Grand Avenue
Suite 201
San Francisco, California 94080

Re: K251790
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: June 10, 2025
Received: June 11, 2025

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.

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,

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)*
K251790

Device Name
SeptAlign

Indications for Use *(Describe)*
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.

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: Tracey Henry
Date Prepared: January 9, 2026

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: SeptAlign (K233569)

IV. DEVICE DESCRIPTION

The SeptAlign System consists of a bioabsorbable implant and single use delivery device. The polydioxanone implant is 190 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 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 delivery cannula and trocar. 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.

These Indications for Use are modified from the predicate but do not change the intended therapeutic, diagnostic, prosthetic, or surgical use of the device: device usage is identical.

The differences do not raise different questions of safety and effectiveness from the predicate device; safety and effectiveness of the device is supported by the clinical evidence provided in the submission.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

There has been no change to the SeptAlign implant. Minor updates to the delivery device and packaging were made to improve ease of use and manufacturability but did not change the technological characteristics of the device.

VII. PERFORMANCE DATA

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

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 testing was performed and demonstrated that the physical and functional requirements were met. Specifically, the following tests were performed to verify the design changes since the predicate: • Deployment/ Simulated Use functionality • Mechanical integrity of handle and deployment mechanism
Performance Testing – Clinical	Safety and efficacy data from two non-significant risk clinical studies conducted in the United States are included to support the modified indications for use. These data were collected as part of two prospective, multi-center, multi-cohort studies in a patient population presenting with a history of nasal obstruction due to mild, moderate and severe nasal septal deviation. <u>Early Feasibility Study</u> For this first-in-human study, various exploratory endpoints were identified including the change in mean Nasal Obstruction Symptom Evaluation (NOSE) score. NOSE responders are defined as ≥20% reduction in NOSE score and/or ≥ 1 clinical category reduction as previously described in the literature. Safety was assessed by characterizing the type and frequency of adverse events reported through the study.

Performance Testing	Data provided
	Seventeen patients with moderate to severe nasal airway obstruction due to mobile, cartilaginous nasal septal deviation were treated with SeptAlign at two study sites in this study. 16/17 subjects received the implant. Of the 16 implanted subjects, 15 received inferior turbinate reduction at the Investigators' discretion. Statistically significant and clinically meaningful improvement in nasal airway obstruction was reported by the majority of study participants at all timepoints and sustained through twelve months post-procedure, at which point the mean NOSE score was reduced 36.0 points from baseline (60.0 to 24.0) with 86.7% considered responders (n=15: one subject lost to follow-up). There were no SAEs or unanticipated AEs reported during the study. Adverse events potentially related to the device and/or procedure included: implant extraction after the subject inserted gauze into the nose and self-extracted the implant, septal perforation who had an off-protocol placement of a second implant placed on top of the mucosa. <u>Pilot Study</u> For the larger Pilot Study, the primary efficacy endpoint was defined as percent change in mean NOSE score from baseline at the three months post-implantation timepoint (at which point the implant is largely degraded). The primary safety endpoint was incidence of Serious Adverse Device Effects (SADEs) through Month 3. Complete data through six-months post-treatment was provided for this submission which includes data from 75 subjects who received the SeptAlign implant treated at 8 study sites. Inclusion criteria included subjects seeking treatment for nasal airway obstruction (NAO) symptoms due primarily to cartilaginous nasal septal deviation with a NOSE score of ≥30. Septal deviation severity was determined per the Investigator's discretion based on the following endoscopic nasal examination criteria: 0=None , 1=Mild, 2=Moderate and 3=Severe. Based on these criteria, approximately 10% of subjects were assessed with "mild" deviations, ~ 50% of subjects were assessed with "moderate" deviations , and the remainder were assessed with "severe" septal deviations. In a subset of thirty subjects assessed, ~75% presented with caudal deflections; and the majority presented with broad-based deflections (versus sharp-angular). Of the 75 implanted subjects, 35 received inferior turbinate reduction at the Investigator's discretion whereas 40 were treated with SeptAlign alone (no concomitant procedures). There were three implant extractions and an additional three subjects were lost to follow-up by the six-month follow-up point. The primary safety and efficacy endpoints were met. Three-months post-procedure, the mean NOSE score for all subjects was reduced 38.5 points from baseline (57.2% reduction in NOSE score, $p<0.0001$)) with 85.1% of subjects considered responders. There were no SADEs reported through this timepoint.

Performance Testing	Data provided
	Results at the six-month follow-up were consistent; the mean NOSE score for all subjects was reduced 42.4 points from baseline (63.2% reduction in NOSE score) with a responder rate of 86.1% (n=62/72). Results for the SeptAlign with inferior turbinate reduction cohort were nearly identical to those for the SeptAlign alone treatment cohort. At 6 months post-treatment, the mean NOSE score for SeptAlign with inferior turbinate reduction was reduced 41.0 points from baseline with 85.7% of subjects (30/35) considered responders; the SeptAlign alone cohort reported a reduction in mean NOSE score of 43.7 points from baseline with 86.5% considered responders (32/37). Septal deviation severity was improved for subjects regardless of baseline severity. There were six subjects rated with "Mild" deviation at Baseline with the mean Baseline score at 72.5. At the Month 3 visit, the mean per subject NOSE score was reduced from Baseline to 34.2 for a mean reduction in NOSE score from baseline of 38.3 points (51.9%). 5 out of 6 participants (83.3%) were responders (defined as either > 1 clinical category reduction or ≥ 20% score reduction). Implanted subjects whose septal deviation was rated "Moderate" at Baseline (n=36), had a mean Baseline score of 62.8 . At the Month 3 visit, the mean per subject NOSE score was reduced from Baseline to 22.5 for a mean reduction in NOSE score from baseline of 40.3 points (62.3%). 34 out of 36 participants (94.4%) were responders. Implanted subjects whose septal deviation was rated "Severe" at Baseline (n=33), had a mean Baseline score was 69.4. At the Month 3 visit, the mean per subject NOSE score was reduced from Baseline to 32.7 for a mean reduction in NOSE score from baseline of 36.7 points (52.5%). 25 out of 33 participants (75.8%) were responders. In addition, the 22-item sino-nasal outcome test (SNOT-22) was administered at Week 1, and Months 1, 3 and 6 after treatment and demonstrated clinically and statistically significant improvements at all timepoints at/after Month 1 ($p \leq 0.001$). Patient-reported satisfaction with the procedure was high and the mean (SD) days to return to work were 2.6 (2.3). Adverse events potentially related to the device and/or procedure included: implant extraction, pain discomfort after procedure, lightheadness, infection/fever/adenopathy. There were a total of 28 device delivery malfunctions during the course of the study related to Investigator's ability to place the implant with the delivery device as specified in the clinical study protocol. Malfunctions did not affect the safety and effectiveness determination in this study as there were no resulting adverse events from any of the malfunctions and physicians were able to successfully place the implant without the delivery device per the Instructions for Use.

Performance Testing	Data provided
	Poolability across clinical sites was assessed using a one-way analysis of variance model with site as a fixed effect. No statistically significant site effect was observed (p=0.5664), supporting pooling of data across clinical sites. One investigator has a financial interest disclosure onfile; study results from the 20 subjects treated at this site are consistent with the study population indicating this financial interest does not introduce bias for the study results. Study Limitation: the nasal septal deviation severity at each site was determined by the Investigator.

No animal performance testing was required to support substantial equivalence.

VIII. CONCLUSIONS

In conclusion, the indications for use have been modified from the predicate device but do not change the intended use. Clinical performance testing supports the expanded indications for use and demonstrate the safety and effectiveness of the SeptAlign device which is substantially equivalent to the predicate device.