July 11, 2025

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

Re: K243655
Trade/Device Name: TurbAlign
Regulation Number: 21 CFR 874.4780
Regulation Name: Intranasal Splint
Regulatory Class: Class I
Product Code: LYA
Dated: June 11, 2025
Received: June 12, 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,

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243566

Device Name

TurbAlign

Indications for Use *(Describe)*

TurbAlign is intended to separate the middle turbinate from the lateral nasal wall during the clinically relevant healing phase associated with sinus surgery (e.g., endoscopic sinus surgery, FESS). The implant provides short-term fixation of the middle turbinate to the nasal septum and thus minimizes the risk of adherence to the lateral nasal wall.

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.

510(k) Summary

I. SUBMITTER

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

Contact Person: Tracey Henry, VP Clinical Affairs, Regulatory, Quality

Date Prepared: July 10, 2025

II. DEVICE

Name of Device:	TurbAlign
Common or Usual Name:	Intranasal splint
Classification Name:	Intranasal splint
Regulatory Class:	Class I
Product Code:	LYA
Regulation Number:	21 CFR 874.4780

III. PREDICATE/REFERENCE DEVICE

Predicate Device: MediENT® Middle Turbinate Implant (K130354)

Reference Device: Spirair Nasal Septal Strap (K223167)

IV. DEVICE DESCRIPTION

TurbAlign™ is a bioabsorbable, polydioxanone implant designed to hold the middle turbinate away from the lateral nasal wall during the clinically relevant healing phase associated with nasal/sinus surgery. The implant includes self-anchoring features (e.g., one "distal anchor" and multiple "proximal anchors") which enable attachment to the middle turbinates for short-term fixation of the middle turbinate to the nasal septum.

TurbAlign includes an attached surgical needle which is inserted into the lateral aspect of the middle turbinate. It is then passed through the nasal septum and then through the contralateral middle turbinate. The implant is then pulled through all three structures until the distal anchor feature is embedded in the first middle turbinate at which time the turbinate is medialized to the septum. The contralateral turbinate is then medialized to the opposite side of the septum using a freer or equivalent and held into place via the proximal anchor. The excess portion of the implant is trimmed off.

The sterile, single-use implant is delivered using standard surgical instruments, such as needle drivers. The implant provides temporary fixation and is fully resorbed over 180 days.

V. INDICATIONS FOR USE

TurbAlign™ is intended to separate the middle turbinate from the lateral nasal wall during the clinically relevant healing phase associated with sinus surgery (e.g., endoscopic sinus surgery, FESS). The implant provides short-term fixation of the middle turbinate to the nasal septum and thus minimizes the risk of adherence to the lateral nasal wall.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The primary technological principle for the subject and predicate devices is to separate the middle turbinate from the lateral nasal wall during the clinically relevant healing phase associated with nasal/sinus surgery. Both devices utilize an absorbable synthetic polymer with sufficient features and resorption to hold the middle turbinate away from the lateral nasal wall. Both devices are single use, provided sterile and made of biocompatible materials.

The subject device differs from the predicate device in that an attached surgical needle is used to enable threading the implant through the relevant tissue structures instead of a hook and barb design. The subject device also has a variable length instead of a fixed length, which is adjustable based on the anatomical need. These differences do not raise different questions of safety or effectiveness. Performance data demonstrates the subject device is as safe and effective as the predicate device.

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 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 subject device do not pose a risk of negative interaction with patients. The implantable portion of the subject device was assessed as a Permanent Implant (>30 Day). The surgical needle was 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	Distribution testing and Accelerated Aging of the implant material and packaging was successfully completed.

Performance Testing	Data provided
Shelf-Life Testing	Final packaging and device performance were successfully tested demonstrating integrity of the sterile barrier and preservation of implant performance for the labeled shelf-life.
Performance Testing – Bench	Mechanical integrity testing of the implant and needle properties was performed and demonstrated that the physical and functional requirements were met. Comparative testing of the features of the subject device to the predicate design features was performed and demonstrated equivalent performance of the device's anchoring features in the relevant tissue. Usability Testing of TurbAlign was performed with qualified, licensed ENT physicians in human cadaver cephalous specimens. Specimens were prepared to simulate the effects of sinus surgery and the TurbAlign implant was successfully placed per the Instructions for Use. In all cases the physicians graded the turbinate position post-TurbAlign placement and confirmed both turbinates were medialized and did not contact the lateral wall.

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

VIII. CONCLUSIONS

In conclusion, the intended use and indications for use for the subject device are the same as that of the predicate device. Performance testing demonstrates equivalent performance of the subject device's features in their ability to medialize tissue during the relevant healing period. Performance testing also demonstrates that any differences in technological characteristics from the predicate device do not affect safety and effectiveness. In conclusion, the subject device is substantially equivalent to the predicate device.