July 25, 2026

Auris Health, Inc.
Shikha Dallas
Director, Regulatory Affairs
5490 Great America Pkwy.
Santa Clara, California 95054

Re: K260382
Trade/Device Name: MONARCH™ Platform (MON-000008)
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: March 13, 2026
Received: March 13, 2026

Dear Shikha Dallas:

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.	K260382

Please provide the device trade name(s).

MONARCH™ Platform (MON-000008)

Please provide your Indications for Use below.

The MONARCH™ Bronchoscope and the Monarch Platform™ and its accessories are intended to provide bronchoscopic visualization of and access to patient airways for diagnostic and therapeutic procedures.

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

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

Please select the age group(s) for which the device(s) is to be used.

- ☐ Neonates/Newborns (Birth to < 29 days old)
- ☐ Infants (29 days old to < 2 years old)
- ☐ Children (2 years old to < 12 years old)
- ☐ Adolescents (12 years old to < 22 years old)
- ☒ Adults (22 years old and greater)

[807.92(a)(1)] Submitter Information

Applicant: Johnson & Johnson MedTech
Auris Health, Inc.
5490 Great America Parkway
Santa Clara, CA 95054
USA
Telephone: 1-800-434-0032 USA
1-650-264-6000 Worldwide

Contact Person: Shikha Dallas
Johnson & Johnson MedTech Auris Health, Inc.
5490 Great America Parkway
Santa Clara, CA 95054
USA
Telephone: 425-236-4604

Date Summary Prepared:
July 24, 2026

[807.92(a)(2)] Name of Device

Device Trade Name: MONARCH™ Platform
Device Common Name: Bronchoscope (Flexible or Rigid)
Device Classification: Class II, 21 CFR 874.4680
Product Code EOQ
Subsequent Product Code JAK

[807.92(a)(3)] Legally Marketed Devices

Predicate Device: MONARCH™ Platform
510(k) #: K243219

[807.92(a)(4)] Device Description

Device Description: The MONARCH™ Platform is intended to provide bronchoscopic visualization of and access to patient airways for diagnostic and therapeutic procedures. The MONARCH™ Platform enables robotic electro-mechanical articulation and precise control of a flexible bronchoscope under continuous and direct control by a physician operator.

The MONARCH™ Platform allows for precise access of the lung anatomy and continuous visualization using the bronchoscope distal tip camera. The MONARCH™ Platform consists of four major components, (1) MONARCH™ Cart, (2) MONARCH™ Tower, (3) MONARCH™ Bronchoscope, (4) MONARCH™ Controller and working channel instruments and accessories. The MONARCH™ Cart provides support for the effector arms. It includes up to three robotic arms and the electronic systems required to power and operate the robotic system. The robotic arms possess multiple degrees of freedom. The MONARCH™ Tower is the primary user's (i.e. physician) procedural display interface. It contains a monitor for user viewing and computers running the system software. The tower provides connectivity for

	the bronchoscope camera. The user controls the system with a controller which transmits user inputs through the electromechanical system to the bronchoscope. The flexible MONARCH™ Bronchoscope has a working channel and a camera at the distal end. Additionally, the MONARCH™ Platform includes electromagnetic (EM) navigation and integrates a pre-operative computed tomography (CT) scan into an intra-operative interface, displaying the modeled bronchoscope tip location relative to the pre-operative scan anatomy. The MONARCH™ Platform is being updated to receive 3D imaging data via an ethernet connection directly from additional models of Cone Beam CT (CBCT) Systems with 3D imaging technology. This will enable real time navigation updates during a procedure with the device. This integration feature is optional for the user, but if selected, use of the MONARCH™ Window Field Generator is required. The modified device includes software updates for navigation and presentation of the anatomy for display and planning purposes, an updated USB stick, and software revisions for the purposes of cybersecurity.
[807.92(a)(5)] Intended Use	
Indications for Use:	The MONARCH™ Bronchoscope and the MONARCH™ Platform and its accessories are intended to provide bronchoscopic visualization of and access to patient airways for diagnostic and therapeutic procedures.
Difference in Indications from Predicate Device:	The intended use of the device is unchanged from the Predicate.
[807.92(a)(6)] Technical Characteristics	
Technological Characteristics:	The substantial equivalence of the MONARCH™ Platform to the Predicates is shown by similarity in intended use, indications for use, and performance. The Subject device and the Predicate device have similar technological characteristics with respect to principles of operation, system design, and performance. The subject and Predicate device achieve the same outcomes. The main design difference of the Subject device is the ability to directly connect to additional models Cone Beam Computed Tomography systems for the purpose of receiving imaging data during a procedure. Performance testing on the Subject device and comparison to the predicate device support that there are no new questions of safety or effectiveness. Like the Predicate MONARCH™ Platform, the modified MONARCH™ Platform is an electromagnetic and image-guided navigation system intended for use during robotically assisted bronchoscopy procedures. Physicians can track and display the real-time location of the

bronchoscope relative to pre-acquired CT images, while simultaneously receiving a live and continuous video image from the bronchoscope, and navigational displays on the device monitor. The modified MONARCH™ Platform may be optionally interfaced to Cone Beam Computed Tomography (CBCT) systems to receive near-real time imaging updates during a procedure. The Subject device of this submission has the same technological characteristics as the Predicate except for updated software and new hardware to facilitate communications with a Cone Beam Computed Tomography system.

Like the Predicate, the MONARCH™ Platform utilizes electromagnetic tracking technology for navigation, uses anatomical reference points on the patient's anatomy for intraoperative registration to the image-based model of the anatomy, and uses CT image sets as reference images for the image-based model. The instructions for use and product labels have been updated to reflect the revised device.

Artificial Intelligence / Machine Learning Information

Like the predicate MONARCH™ Platform, K243219, the proposed device employs Machine Learning in the development of certain Device Software Functions which are considered to be Artificial Intelligence. The AI software in the MONARCH™ Platform, Bronch 4.2 uses Machine Learning to train the following static Device Software Functions.

- Bronchoscope tip localization - The Navigation software includes a vision-based AI/ML algorithm for estimating the position and orientation of the scope tip.
- 3D Airway Model Segmentation - The Pre-Operative Planning software uses an AI/ML algorithm for generating a 3D model of the patient lung airways and displays it to the user.
- Nodule Segmentation - The Pre-Operative Planning software utilizes an AI/ML algorithm to generate a 3D model (representation) and boundary surface of the nodule within the CT scan based on the user-selected location.

The remaining Device Software Functions in the proposed device do not use AI/ML functions.

The AI/ML functions in the MONARCH™ Platform are not user selectable, and do not require software inputs from other software sources. The physician user makes all decisions to the setup of the room, planning, and navigation of the patient’s airways. These Device software functions assist users to navigate of the

bronchoscope to the desired anatomy, as part of its fulfillment of the devices, intended use, to provide bronchoscopic visualization of and access to patient airways for diagnostic and therapeutic procedure

Refer to table below for a Comparison of Technological Characteristics with the Predicate device.

Key Attributes	Predicate Device Auris Health, Inc. MONARCH™ Platform K243219	Subject Device Auris Health, Inc. MONARCH™ Platform	Comparison
Regulatory Classification Information	Regulation Number: 21 CFR 874.4680 Regulation Name: Bronchoscope (Flexible or Rigid) And Accessories Regulatory Class: Class II Product Code: EOQ	Regulation Number: 21 CFR 874.4680 Regulation Name: Bronchoscope (Flexible or Rigid) And Accessories Regulatory Class: Class II Product Code: EOQ	Same. The Predicate device and Subject device have the same regulatory classification information.
Device Description	The MONARCH™ Platform is intended to provide bronchoscopic visualization of and access to patient airways for diagnostic and therapeutic procedures. The MONARCH™ Platform enables robotic electro-mechanical articulation and precise control of a flexible bronchoscope under continuous and direct control by a physician and allows for precise access of the lung anatomy and continuous visualization using the bronchoscope distal tip camera, under the control of a physician operator. Additionally, the MONARCH™ Platform can integrate imaging data directly from a Cone Beam Computed Tomography system to update the scope and target position to overcome any changes in anatomy not reflected in the pre-op CT scan.	The MONARCH™ Platform is intended to provide bronchoscopic visualization of and access to patient airways for diagnostic and therapeutic procedures. The MONARCH™ Platform enables robotic electro-mechanical articulation and precise control of a flexible bronchoscope under continuous and direct control by a physician and allows for precise access of the lung anatomy and continuous visualization using the bronchoscope distal tip camera, under the control of a physician operator. Additionally, the MONARCH™ Platform can integrate imaging data directly from a Cone Beam Computed Tomography system to update the scope and target position to overcome any changes in anatomy not reflected in the pre-op CT scan.	Equivalent. Compared to the Predicate Device, the Subject Device has been equipped with updated software to optionally enable receipt of imaging data directly from Siemens Cone Beam CT Systems via NaviLink interface, to update the scope and target position to overcome changes in anatomy not reflected in the pre-op CT scan. The predicate device incorporated a similar interface with GE OEC 3D systems. Additional changes were made to update software relating to navigation, nodule segmentation, and to provide cybersecurity updates. The difference do not raise new questions of safety or efficacy.
Intended use / Indications for use	The MONARCH Bronchoscope and the MONARCH™ Platform and its accessories are intended to provide bronchoscopic visualization of and access to patient airways for diagnostic and therapeutic procedures.	The MONARCH Bronchoscope and the MONARCH™ Platform and its accessories are intended to provide bronchoscopic visualization of and access to patient airways for diagnostic and therapeutic procedures.	The predicate and subject device have identical Intended use / Indications for Use statements.

Key Attributes	Predicate Device Auris Health, Inc. MONARCH™ Platform K243219	Subject Device Auris Health, Inc. MONARCH™ Platform	Comparison
Fundamental scientific technology	Electromechanical system using direct (camera and light source) supplemented by indirect (electromagnetic navigation) visualization of the flexible bronchoscope position by the physician operator. Steering, as well as insertion and withdrawal is under continuous and direct control by the physician operator.	Electromechanical system using direct (camera and light source) supplemented by indirect (electromagnetic navigation) visualization of the flexible bronchoscope position by the physician operator. Steering, as well as insertion and withdrawal is under continuous and direct control by the physician operator.	Same. The Predicate and Subject devices have the same fundamental scientific technology.
Primary mode of action	Physician input (movement of endoscopic controller) to move the endoscope.	Physician input (movement of endoscopic controller) to move the endoscope.	Same. The primary mode of action is unchanged between the Predicate and Subject device.
Method of distal tip movement	Pull wires	Pull wires	Same. The method of distal tip movement is unchanged between the Predicate and Subject device.
Major components	Auris Cart Auris Tower Bronchoscope and Sheath Accessories (working channel instruments, patient introducer adaptor, fluidics tubing, navigation field generators, field generator mount, USB stick, patient sensors, patient patches, etc.).	Auris Cart Auris Tower Bronchoscope and Sheath Accessories (working channel instruments, patient introducer adaptor, fluidics tubing, navigation field generators, field generator mount, USB stick, patient sensors, patient patches, etc.).	Same. The Predicate and Subject devices are comprised as the same major components.
Control/physician interfaces	Controller with joystick and buttons.	Controller with joystick and buttons.	Same. The Predicate and Subject devices feature the same Control/physician interfaces.
Cart base elements	Touch screen monitor and embedded PC.	Touch screen monitor and embedded PC.	Equivalent. The Predicate and Subject devices have the same cart base elements; however, the modified device includes updated software.

Key Attributes	Predicate Device Auris Health, Inc. MONARCH™ Platform K243219	Subject Device Auris Health, Inc. MONARCH™ Platform	Comparison
Robotic arms	Two identical arms (2).	Two identical arms (2).	Same. The Predicate and Subject device have the same number of arms.
Tower key characteristics	Touch screen monitor, on-board computers, fluidics pump, power supply.	Touch screen monitor, on-board computers, fluidics pump, power supply.	Equivalent. The tower in the modified device includes updated software.
Electromagnetic Navigation	Yes	Yes	Same. The Predicate and Subject Devices both include Electromagnetic Navigation.
Working channel Instruments	Aspirating biopsy needles, Biopsy Forceps, Cytology Brush. Third party compatible (meet working channel length and diameter requirements) instruments and tools (e.g., RBUS probe)	Aspirating biopsy needles, Biopsy Forceps, Cytology Brush. Third party compatible (meet working channel length and diameter requirements) instruments and tools (e.g., RBUS probe).	Same. The Predicate and Subject Devices are both compatible with the same working channel accessories.
Navigation and segmentation	• Bronchoscope tip localization • 3D Airway Model Segmentation • Nodule Segmentation	• Bronchoscope tip localization • 3D Airway Model Segmentation • Nodule Segmentation	Equivalent. Both the subject device and predicate device provide nodule segmentation, however the subject device allows the user to identify a nodule via a single-click, or optionally to select the target by dragging across the displayed image. The revised functionality employs a static algorithm based on annotated images. Both the subject device and predicate device have a physician defined navigation path, however the subject device has a modification that is limited to path smoothing and does not affect the safety or performance of the feature. The change does not raise new questions of safety and efficacy.

Key Attributes	Predicate Device Auris Health, Inc. MONARCH™ Platform K243219	Subject Device Auris Health, Inc. MONARCH™ Platform	Comparison
Anatomical position indicator	Stylized humanoid figure	Stylized humanoid figure & optional "compass" overlay	Equivalent. The subject device offers an optional compass overly for assisting users in confirming anatomical position and direction of view. The change does not raise new questions of safety and efficacy as both methods confirm orientation.
Direct Interface with CBCT system to reduce potential body divergence.	Implemented.	Implemented.	Equivalent. Compared to the predicate, the subject device can integrate imaging data directly from additional models of Cone Beam Computed Tomography system during a procedure to update the scope and target position to overcome changes in anatomy not reflected in the pre-op CT scan.

Non-clinical Performance Data:

The MONARCH™ Platform was tested to ensure that it functions in accordance with the system design specifications related to substantial equivalence in terms of device safety and effectiveness.

The following nonclinical tests were performed:

1. Proof of Design electrical tests, to verify all hardware modules perform within specifications.
2. Location Accuracy tests
3. Software functional tests, covering the complete system functionality, and including error handling, usability and time
4. Simulated use accuracy test, in which a complete CT image registration and instrument navigation workflow was performed, to verify the overall accuracy of the system.
5. Pre-clinical (cadaver) tests were designed to mimic surgical procedures using the MONARCH™ Platform in a simulated clinical environment, to assess the execution of a complete robotically assisted bronchoscopy procedure workflow and to qualitatively estimate the system clinical accuracy.
6. The proposed MONARCH™ Platform passed all tests in accordance with appropriate test criteria and standards, and the modified device did not raise new questions of safety or effectiveness.

Clinical Performance Data:

Clinical data was not necessary to determine that the MONARCH™ Platform was substantially equivalent to the Predicate device. The performance data demonstrated that the device performs as intended.

Conclusion:

The modified MONARCH™ Platform is substantially equivalent to the currently cleared MONARCH™ Platform based on the completion of non-clinical bench testing as well as similar principles of design, operation and indications for use.