January 23, 2025

Auris Health, Inc.
Amy Clendening-Wheeler
Sr Regulatory Affairs Specialist
5490 Great America Parkway
Santa Clara, California 94054

Re: K243219
Trade/Device Name: MONARCH™ Platform
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: December 26, 2024
Received: December 26, 2024

Dear Amy Clendening-Wheeler:

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
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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)*

K243219

Device Name

MONARCH™ Platform

Indications for Use *(Describe)*

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.

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.

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510(k) Summary
MONARCH™ Platform
K243219

[807.92(a)(1)] Submitter Information

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Amy Clendening-Wheeler
Sr. RA Specialist

Date Summary Prepared: January 23, 2025

[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) #: K211493

[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 (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 and lighting, as well as the fluidics system. The user controls the system

with an endoscopic 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. The working channel of the Bronchoscope is used for irrigation, aspiration and to deliver the working channel instruments.

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 a Cone Beam CT (CBCT) System 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, firmware updates for a revised controller, and hardware 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 Indications for Use have been updated from the predicate K211493, however they have not materially changed. The Indications for Use statement cleared in K211493 are "The Monarch Platform and its accessories are intended to provide bronchoscopic visualization of and access to patient airways for diagnostic and therapeutic procedures." The Indications for Use in this submission have been updated to reflect the essential role of the bronchoscope and now reads: "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."

[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; however, the main design difference of the subject device is the ability to directly connect to 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 reference 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. Refer to Table 1 on the following pages for a Comparison of Technological Characteristics with the Predicate device.

Table 1: Comparison of Predicate & Subject Device of this Submission

Key Attributes	Predicate Device Auris Health, Inc. MONARCH Platform K211493	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.	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.	Different. Compared to the Predicate Device, the Subject Device has been equipped with additional hardware and software to optionally enable receipt of imaging data directly from a Cone Beam Computed Tomography System, to update the scope and target position to overcome changes in anatomy not reflected in the pre-op CT scan.[1] Additional changes were made to update certain hardware, and to implement Cybersecurity countermeasures.
Intended use / Indications for use	The MONARCH Platform is 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.	Equivalent. The verbiage of the Intended Use / Indications for Use has been updated to reflect the contribution of the previously cleared MONARCH Bronchoscope in the MONARCH Platform meeting its Intended Use and Indications for Use.
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	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	Same. The fundamental scientific technology, consisting of an electromechanical system using direct (camera and light source) inputs supplemented by indirect (electromagnetic navigation) visualization of the flexible bronchoscope position by the physician operator is

Key Attributes	Predicate Device Auris Health, Inc. MONARCH Platform K211493	Subject Device Auris Health, Inc. MONARCH Platform	Comparison
	by the physician operator.	by the physician operator.	unchanged. Like the predicate, steering, including insertion and withdrawal, remains under continuous and direct control by the physician operator. Additionally, the Subject device can integrate imaging data directly from a 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.
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 Predicate and Subject devices have the same primary modes of action.
Method of distal tip movement	Pull wires	Pull wires	Same. The Predicate and Subject devices have the same mechanism of distal tip movement.
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 (Inner Scope and Outer Sheath) Accessories (working channel instruments, patient introducer adaptor, fluidics tubing, navigation field generator, 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 an additional Ethernet connection for the interface Cone Beam Computed Tomography System data.
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, door lock.	Equivalent. The Tower in Predicate and Subject devices have largely the same key characteristics, however the Subject device has been equipped with a door lock for cybersecurity purposes.

Key Attributes	Predicate Device Auris Health, Inc. MONARCH Platform K211493	Subject Device Auris Health, Inc. MONARCH Platform	Comparison
Electromagnetic Navigation	Yes	Yes	Same. The Predicate and Subject Devices both include Electromagnetic Navigation.
Working channel instruments	Auris Aspirating biopsy needle, Biopsy Forceps, Cytology Brush Third party compatible (meet working channel length and diameter requirements) instruments and tools (e.g., RBUS probe)	Auris Aspirating biopsy needle, Biopsy Forceps, Cytology Brush (cleared in K211493) 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.
Direct Interface with CBCT system to reduce potential body divergence.	Not available	Implemented – subject of this submission.	Different. Compared to the predicate, the subject device can integrate imaging data directly from a 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. [1]

Reference Device Noah Medical Galaxy System™ K223144	[1]The Galaxy System, K223144 may be considered a reference device, as K223144 was cleared with a description including "full procedure navigation that integrates a pre-operative computed tomography scan to display scope tip location relative to the pre-operative scan anatomy. Additionally, Galaxy integrates a tomosynthesis spin to update the scope and target position to overcome any changes in anatomy not reflected in the pre-op CT scan." Note: the reference to K223144 is included for informational purposes only, and is not intended to serve as a decision point for determination of Substantial Equivalence.

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 to verify the modified device continued to meet performance specifications:

1. Proof of Design electrical tests, to verify all hardware modules perform within specifications.
2. Location accuracy tests for navigation purposes.
3. Software functional tests, covering the complete system functionality, and including error handling, usability, time and the ability to receive, process, and display imaging data from cone beam CT Systems.
4. Safety, EMC, and mechanical tests were performed by an independent nationally recognized testing laboratory to verify compliance with safety and EMC standards for medical devices to address hardware changes.
5. 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.
6. Usability (Human Factors) 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.
7. 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 modified 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.