April 15, 2020

Auris Health, Inc.
Anna Libman
Director Regulatory Affairs
150 Shoreline Drive
Redwood City, California 94065

Re: K193534
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: March 13, 2020
Received: March 16, 2020

Dear Anna Libman:

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for Michael J. Ryan
Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Monarch Platform

Indications for Use *(Describe)*
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.

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

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

I. SUBMITTER

Address:
Auris Health, Inc.
150 Shoreline Drive,
Redwood City, CA 94065

Contact Person:
Anna Libman
Director, Regulatory Affairs
anna.libman@aurishealth.com
408-204-3370

Date Prepared: December 18, 2019

II. DEVICE

Manufacturer:	Auris Health., Inc.
Trade/Proprietary Name:	Monarch Platform
Common Name:	Bronchoscope (flexible or rigid) and accessories
Product Code:	EOQ
Regulatory Class:	Class II
Classification:	21 CFR§874.4680 Bronchoscope (flexible or rigid) and accessories
Product Codes:	EOQ, JAK

III. PREDICATE DEVICE(S)

Manufacturer:	Auris Health., Inc. (Formerly Auris Surgical Robotic, Inc.)
Trade name:	Monarch Endoscopy Platform (Monarch Platform)
510(k) Number:	K173760
Classification Name:	21 CFR§874.4680 Bronchoscope (flexible or rigid) and accessories
Product Codes:	EOQ, JAK

IV. 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 three major components, (1) Monarch Cart, (2) Monarch Tower, and (3) Monarch Bronchoscope, and working channel instruments and accessories. The Monarch Cart provides support for the effector arms. It includes 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 tip. The working channel of the Bronchoscope is used for irrigation, aspiration and to deliver the working channel instruments. The single-use manually controlled Auris instruments compatible with the Monarch Platform include the Aspirating Biopsy Needle, Biopsy Forceps, and Cytology Brush.

Additionally, the Monarch Platform includes electromagnetic (EM) navigation that 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.

V. INDICATIONS FOR USE

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

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Overall, the subject, predicate and reference devices are based on the following similar basic technological elements:

Key Attributes	Predicate Device Monarch Endoscopy Platform K173760	Subject Device Monarch Platform
Regulation Number	21 CFR §874.4680, Bronchoscope (flexible or rigid) and accessories	21 CFR §874.4680, Bronchoscope (flexible or rigid) and accessories
Class	II	II
Product Code	EOQ, Bronchoscope (Flexible Or Rigid)	EOQ, Bronchoscope (Flexible Or Rigid)

	JAK, System, X-Ray, Tomography, Computed	JAK, System, X-Ray, Tomography, Computed
Indications for Use	The Monarch Endoscopy Platform (Monarch Platform) and its accessories are intended to provide bronchoscopic visualization of and access to patient airways for diagnostic and therapeutic procedures.	The Monarch Platform and its accessories are intended to provide bronchoscopic visualization of and access to patient airways for diagnostic and therapeutic procedures.
Major components	• Auris Cart • Auris Tower • Bronchoscope (Scope and Sheath) • Accessories (working channel instruments, patient introducer adaptor, fluidics tubing, navigation field generator, field generator mount, USB stick, patient sensors, patient patches, etc.)	• Auris Cart • Auris Tower • Bronchoscope (Scope and Sheath) • Accessories (working channel instruments, patient introducer adaptor, fluidics tubing, navigation field generator, field generator mount, USB stick, patient sensors, patient patches, etc.)
Robotic arms	• Two identical arms (2) • Built-in instrument device manipulator (IDM) • Arm weight: 26 lbs.	• Three identical arms (3) • Built-in instrument device manipulator (IDM) • Arm weight: 26 lbs.
Bronchoscope use	• Single-use, sterile	• Single-use, sterile
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 K173760) • Third party compatible (meet working channel length and diameter requirements) instruments and tools (e.g., RBUS probe)

VII. PERFORMANCE DATA

Verification and validation testing were conducted for the Monarch Platform to ensure that the system performs as intended to meet its intended use and to ensure that differences in technological characteristics between the Monarch Platform and the predicate do not raise different questions of safety or effectiveness.

Biocompatibility

The Monarch Platform patient contacting materials were evaluated for biocompatibility in accordance with the provisions of the guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" Guidance for Industry and Food and Drug Administration Staff issued

on: June 16, 2016. The results demonstrate that the Monarch Platform is biocompatible for its intended use.

Electrical Safety and Electromagnetic Compatibility
The Monarch Platform has been fully evaluated and tested for EMC compliance and electrical safety to the following standards: AAMI/ANSI ES60601-1, IEC 60601-1-2, IEC 60601-1-6, and IEC 60601-2-18**.**

Verification Testing
System Level Tests were executed to verify the overall functionality of the Monarch Platform to operate as specified by the design input requirements including pre-operative planning, workflow, latency, various functional safety features, irrigation/aspiration, and other general functionality. Sub-system level requirements for safety and efficacy of the system, including but not limited to the adherence to regulatory standards were verified. Results of verification testing confirm that the Monarch Platform conforms to design specifications and meets the needs of the intended users. The device met all applicable design input requirements, satisfied all sub-system specifications, and exhibit the electrical, mechanical and functional integrity necessary.

Validation Testing
Auris performed animal and cadaver testing to evaluate the Monarch Platform under simulated use conditions to validate the user needs, including the safety and effectiveness of the system as per its intended clinical use. These studies demonstrated that the Monarch Platform design meets the intended user requirements and facilitates safe and effective use.

Human Factors and Usability Testing
Auris performed human factors and usability testing for the Monarch Platform. Simulated use testing was performed in accordance with finalized guidance: "Applying Human Factors and Usability Engineering to Medical Devices" issued February 3, 2016. This testing assessed the Monarch Platform for safety and effective use by representative users during a simulated use bronchoscopy procedure after training on using the Monarch Platform.

VIII. CONCLUSION

The Monarch Platform and the predicate device have the same intended use, same indications for use, and highly similar technological characteristics. The testing verified and validated through performance testing that the device performs as intended to its specifications and meets its intended use. Any differences between the subject and predicate device have been evaluated and found to not raise different questions of safety or effectiveness. As such, the subject device is substantially equivalent to the predicate device and the minor differences in technological characteristics between the two devices do not raise different questions of safety or effectiveness.