July 9, 2021

Auris Health, Inc.
Shikha Gola
Director of Regulatory Affairs
150 Shoreline Drive
Redwood, California 94065

Re: K211493
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: June 15, 2021
Received: June 21, 2021

Dear Shikha Gola:

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 Shu-Chen Peng
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)*
K211493

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.

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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.

510(k) Number K211493

I. SUBMITTER

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

Contact Person:
Shikha Gola
Director, Regulatory Affairs
sgola@its.jnj.com
201-240-3891

Date Prepared: May 11, 2021

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.
Trade/Proprietary Name:	Monarch Platform
510(K)	K193534
Classification:	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 robotic arms. It includes up to three robotic arms and the electronic systems required to power and operate the robotic system. 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.

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. Two options of field generators are available to enable electromagnetic navigation. The current Monarch Navigation Field Generator and a new Window Field Generator (WFG). The new WFG is being added to increase compatibility of the Monarch system with advanced imaging systems (Cone Beam and Mobile CT).

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

The Monarch Platform is substantially equivalent to the predicate device with respect to the device function, design and indications of use. There are no changes to the key components of the Monarch Platform which includes the Monarch Cart, Monarch Tower and Monarch Bronchoscope. The proposed device modifications introduced the Window Field Generator (WFG) as an optional accessory for customers for increased mechanical compatibility with advanced imaging systems. This new WFG has the same core technological characteristics as the current Monarch Field Generator but is secured under the patient bed to optimize mechanical compatibility. Both EM field generators perform the same function for the Monarch Platform. Minor software changes were also made to the arm kinematics to better accommodate high patient bed heights. Additionally, navigation was updated for smoother virtual views when transitioning between predicted airways. These updates helped improve the navigation image displayed on the user interface. An additional condition for which a “Segmentation

Failure" notification would be triggered during the procedure planning step was also added. Lastly the red saturation in the live endoscopy view was reduced to better reflect real tissue coloration. These changes did not impact the core technological characteristics of the Monarch Platform.

Device Characteristics	Predicate Device Auris Health, Inc. Monarch Platform (K193534)	Subject Device (K211493)
Regulation Number	21 CFR §874.4680, Bronchoscope (flexible or rigid) and accessories	Same
Class	II	Same
Product Code	EOQ, Bronchoscope (Flexible Or Rigid) JAK, System, X-Ray, Tomography, Computed	Same
Intended Use	The Monarch Platform and its accessories are intended to provide bronchoscopic visualization of and access to patient airways for diagnostic and therapeutic procedures.	Same
Contraindications for Use	Contraindications include but are not limited to: • Patient whose general health or respiratory function or both are compromised to the point that the patient would not tolerate flexible bronchoscopy. • Absence of a trained bronchoscopist to perform or closely and directly supervise the procedure, as well as manage complications common to flexible bronchoscopy. • Use of the system in patients with electrically or magnetically activated implanted medical devices.	Same

VII. PERFORMANCE DATA

Verification and validation testing for the new Window Field Generator and the Monarch system were conducted to ensure that the system performs as intended and to ensure the changes outlined in this submission do not raise different questions of safety or effectiveness. Verification testing included electrical safety and electromagnetic

compatibility, software, and performance specifications verification testing. In addition to design verification, confirmatory validation testing was performed to ensure the device meets its Clinical Input Requirements (CIR) for its intended use. Validation Testing included evaluations of the pertinent parts of workflow impacted by this change with accredited bronchoscopists. Overall, device performance testing showed that the differences in technological characteristics do not raise different questions of safety or effectiveness.

VIII. CONCLUSION

The modified device in this submission does not affect the intended use of the device or alter the fundamental scientific technology of the device. Summary information for the design control process serves as the basis for this submission. The Monarch Platform is substantially equivalent to the legally marketed predicate device based upon intended use, technological characteristics and performance testing.