November 28, 2023

Auris Health Inc., a Johnson and Johnson Family Company
Patrick Garvey
Director, Regulatory Affairs
150 Shoreline Drive
Redwood City, California 94065

Re: K231473
Trade/Device Name: Monarch Bronchoscope
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: QNW
Dated: October 30, 2023
Received: October 31, 2023

Dear Patrick Garvey:

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.

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
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)*
K231473

Device Name
Monarch Bronchoscope

Indications for Use *(Describe)*
The reprocessed Monarch Bronchoscope, used in conjunction with the Monarch Platform, is 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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General Information

510(k) Submitter	Auris Health, Inc. 150 Shoreline Drive Redwood City, CA 94065 USA
Original Device Manufacturer	Auris Health, Inc. 150 Shoreline Drive Redwood City, CA 94065 USA
FDA Registration Number	3014447948
Reprocessed Device Manufacturer	Sterilmed, Inc., a Johnson and Johnson Family Company 5010 Cheshire Pkwy N, Suite 2, Plymouth, MN 55446
FDA Registration Number	3011276773
Primary Correspondent	James Patrick Garvey II Director, Regulatory Affairs Auris Health, Inc.
Contact Information	Email: pgarvey@its.jnj.com Phone: (650) 590-6907
Date Prepared	28 November 2023

Device Identification

Proposed Reprocessed Device:

Proprietary Name	Monarch Bronchoscope
Common Name	Reprocessed Bronchoscope
Classification Name	Bronchoscope (flexible or rigid) and accessories
Regulation Number	21 CFR 874.4680
Product Code	QNW
Regulatory Class	II
Model Number	MBR-000211-B

Primary Predicate Device:

Proprietary Name	Monarch Bronchoscope
Common Name	Reprocessed Bronchoscope
Premarket Notification	K203614
Classification Name	Bronchoscope (flexible or rigid) and accessories
Regulation Number	21 CFR 874.4680
Product Code	QNW
Regulatory Class	II
Model Number	MBR-000211-B

Secondary Predicate OEM Device:

Proprietary Name	Monarch Platform
Common Name	Bronchoscope (Flexible or Rigid)
Premarket Notification	K193534
Classification Name	Bronchoscope (flexible or rigid) and accessories
Regulation Number	21 CFR 874.4680
Product Code	EOQ
Regulatory Class	II
Model Number	MBR-000211-A

Device Description

The 4x reprocessed Monarch Bronchoscope, MBR-000211-B, (hereafter referred to as "Proposed Device") is similar to the 2x reprocessed Monarch Bronchoscope, MBR-000211-B, (hereafter referred to as "Predicate Device").

The Original Monarch Bronchoscope, MBR-000211-A, (hereafter referred to as "Co-Predicate Device") cleared under K193534 is identical to the 2x reprocessed Monarch Bronchoscope ("Predicate Device"), cleared under K203614.

Both device designs are controlled by Auris Health, Inc., throughout their total product lifecycle.

The Monarch Bronchoscope is a component of, and must be used with, the Monarch Platform, cleared under K193534. The Monarch Bronchoscope is connected to the robotic arms of the Monarch Platform to provide bronchoscopic visualization of and access to patient airways for diagnostic and therapeutic procedures. The Proposed Device is a reprocessed single-use device that is either discarded or returned to Auris for reprocessing after clinical use. The original single-use Monarch Bronchoscope was cleared for one clinical use under K193534. The reprocessed single-use (rSUD) Monarch Bronchoscope was cleared for two (2) clinical uses under K203614. This premarket notification intends to gain market clearance for a reprocessed single-use (rSUD) Monarch Bronchoscope that can be reprocessed up to three (3) times, for a total of four (4) clinical uses.

Identical to the Predicate Device, the Reprocessed Monarch Bronchoscope, consisting of the Inner Scope ("scope") and the Outer Sheath ("sheath"), has 4-way articulation controlled by continuous, direct, visual control of the physician using the Monarch Platform. The Proposed Device contains a working channel through which biopsy devices, or other working channel instruments, may be introduced. The distal tip of the Proposed Device has a camera control unit (CCU) that collects live images that are then transmitted to the physician's display interface of the Monarch Platform. The camera transmits vision data to the Monarch Tower through the camera cable. The single-use, manually controlled, working channel instruments compatible with the Proposed Device are identical to the working channel instruments compatible with the Predicate Device.

Intended Use/Indications for Use

The reprocessed Monarch Bronchoscope, used in conjunction with the Monarch Platform, is intended to provide bronchoscopic visualization of and access to patient airways for diagnostic and therapeutic procedures.

Summary of Key Technological Characteristics

The Proposed Device is a single-use device similar to the Predicate Device in design. Both devices have the same clinical applications, patient population, performance specifications, and principles of operation. All key technological characteristics including articulation, vision, and compatibility with working channel instruments are identical. Key technological characteristics are listed in the table below.

Key Attributes	Proposed Device (MBR-000211-B)
Product Code	QNW
Regulation Number	21 CFR 874.4680
Classification	II
Intended for Single Use	Yes
Field of View (FOV) in air	90 degrees
Direction of view	0 degrees
FOV depth	3-30mm
Imaging type	CMOS Imager
Illumination type	LED
Active angulation degrees up/down or 4 directions	180/180/180/180
Pixel resolution	200 x 200
Camera lens	Aluminosilicate glass
Light source	LED (covered in cyanoacrylate adhesive)
Working Channel Instruments Compatibility	Auris working channel instruments and third party instruments that meet working channel length and diameter requirements (e.g., REBUS probe)

This premarket notification is submitted to demonstrate the ability to reprocess the Monarch Bronchoscope three (3) times without impacting safety or effectiveness as compared to the predicate device. Reprocessing of the device includes removal of adherent soil and decontamination. Each individual device is tested for appropriate function of its components prior to packaging, labeling, and sterilization operations.

Performance Testing

The Reprocessed Monarch Bronchoscope was tested for performance in accordance with internal design specification and with the applicable performance standards to demonstrate safety and effectiveness to support substantial equivalence. This includes the following tests:

Test Name	Description	Results
Cleaning Validation	Ensures the device can be returned to a like new condition. Worst case device conditioning was taken into consideration while conducting this testing.	Pass
Functional Performance and System Compatibility	Functional performance and system compatibility were performed to verify the performance of the Proposed Device was not negatively impacted by reprocessing. Worst case device conditioning was taken into consideration while conducting this testing.	Pass
Electromagnetic Compatibility and Electrical Safety	The Proposed Device has been fully evaluated for electrical safety and EMC compliance to the following standards: AAMI/ANSI ES60601-1, IEC 60601-1-2, and IEC 60601-2-18.	Pass
Biocompatibility	Evaluates the end of life biocompatibility of the limited contact device in accordance with ISO 10993-1:2018. Worst case device conditioning was taken into consideration while conducting this testing.	Pass
Sterilization	Sterilization was assessed in accordance with ISO 11135: 2018. Sterilization residuals were assessed in accordance with ISO 10993-7:2008. The Proposed Device uses a validated ethylene oxide sterilization process using a half-cycle overkill approach to achieve a minimum sterility assurance level of 10^{-6}.	Pass

The performance testing demonstrates that the 4x reprocessed Monarch Bronchoscope is as safe and effective as the legally marketed 2x reprocessed Monarch Bronchoscope and operates as originally intended.

Conclusion

The indications for use/intended use, clinical applications, patient population, performance specifications, technological characteristics, biological safety, and principles of operation of the Proposed Device are identical to the Predicate Device.

Test results demonstrated substantial equivalence to the Predicate Device with respect to safety and effectiveness. We therefore conclude that the 4x reprocessed Monarch Bronchoscope is as safe, and effective as, and substantially equivalent to the Predicate Device, 2x reprocessed Monarch Bronchoscope.

The following device is included in this submission:

Description	**OEM Model Number**	**Reprocessed Model Number**
Monarch Bronchoscope	MBR-000211-A	MBR-000211-B