



March 22, 2018

Auris Surgical Robotics, Inc.  
Joy Sacmar  
Vice President, RA/QA  
150 Shoreline Road  
Redwood City, CA 94065

Re: K173760  
Trade/Device Name: Monarch Endoscopy Platform (Monarch Platform)  
Regulation Number: 21 CFR 874.4680  
Regulation Name: Bronchoscope (Flexible or Rigid) and Accessories  
Regulatory Class: Class II  
Product Code: EOQ  
Dated: February 21, 2018  
Received: February 22, 2018

Dear Joy Sacmar:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

  
**Eric A. Mann -S**

for Malvina B. Eydelman, M.D.  
Director  
Division of Ophthalmic and Ear, Nose,  
and Throat Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K173760

Device Name

Monarch Endoscopy Platform (Monarch Platform)

Indications for Use (Describe)

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.

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.

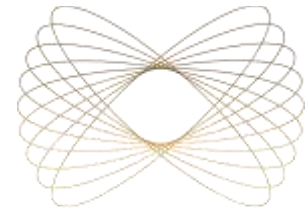
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**AURIS**

## **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:**     K173760    

### **I. SUBMITTER**

Auris Surgical Robotics, Inc.  
150 Shoreline Drive  
Redwood City, CA 94065

Contact Person: Joy Sacmar, Vice President RA/QA  
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Phone/Fax: (650) 781-1610  
Mobile: (408) 306-3537

Date Prepared: December 7, 2017  
Prepared By: Elizabeth Osuna, Senior Regulatory Affairs Specialist

### **II. DEVICE**

Trade/Device Name: Monarch Endoscopy Platform (Monarch Platform)  
Common Name: Bronchoscope (flexible or rigid) and accessories  
Classification Name: Bronchoscope (flexible or rigid) and accessories  
Product Code: EOQ  
Regulatory Class: Class II  
Regulation Number: 21 CFR 874.4680

Trade/Device Name: Aspirating Biopsy Needle  
Common Name: Bronchoscope (flexible or rigid) and accessories  
Classification Name: Bronchoscope (flexible or rigid) and accessories  
Product Code: EOQ  
Regulatory Class: Class II  
Regulation Number: 21 CFR 874.4680

Trade/Device Name: Biopsy Forceps  
Common Name: Bronchoscope (flexible or rigid) and accessories  
Classification Name: Bronchoscope (flexible or rigid) and accessories  
Product Code: EOQ  
Regulatory Class: Class II  
Regulation Number: 21 CFR 874.4680

Trade/Device Name: Cytology Brush  
Common Name: Bronchoscope (flexible or rigid) and accessories  
Classification Name: Bronchoscope (flexible or rigid) and accessories  
Product Code: EOQ  
Regulatory Class: Class II  
Regulation Number: 21 CFR 874.4680

### **III. PREDICATE DEVICE(S)**

Trade name: Karl Storz Bronchoscope  
510(k) Number: K071530  
Classification Name: Bronchoscope (flexible or rigid) and accessories  
21 CFR 874.4680  
Product Code: EOQ  
Manufacturer: Karl Storz Endoscopy-America, Inc.

Trade name: PeriFLEX Transbronchial Aspiration Needle  
510(k) Number: K162611  
Classification Name: Bronchoscope (flexible or rigid) and accessories  
21 CFR 874.4680  
Product Code: EOQ  
Manufacturer: Spiration, Inc.

Trade name: Olympus FB series biopsy forceps  
510(k) Number: K962555  
Classification Name: Bronchoscope (flexible or rigid) and accessories  
21 CFR 874.4680  
Product Code: EOQ  
Manufacturer: Olympus America, Inc.

Trade name: Wang Bronchial Needle Brush  
510(k) Number: K944650  
Classification Name: Bronchoscope (flexible or rigid) and accessories  
21 CFR 874.4680  
Product Code: EOQ  
Manufacturer: Mill-Rose Laboratory

In compliance with FDA Guidance “The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]” we are including the following as a reference device:

Trade name: Auris Robotic Endoscopy System (ARES)  
510(k) Number: K152319  
Manufacturer: Auris Surgical Robotics, Inc.

Trade name: superDimension™ Navigation System  
510(k) Number: K151376  
Manufacturer: Covidien LLC.

Trade name: superDimension™, SuperTrax Transbronchial Aspirating Needle  
510(k) Number: K860582  
Manufacturer: Covidien LLC.

Trade name: superDimension™, SuperTrax Biopsy Forceps  
510(k) Number: K925392  
Manufacturer: Covidien LLC.

Trade name: superDimension™ Cytology Brush  
510(k) Number: K834402  
Manufacturer: Covidien LLC.

#### **IV. DEVICE DESCRIPTION**

The Monarch™ Endoscopy Platform (Monarch Platform) is intended to be used by qualified physicians to provide bronchoscopic visualization of and access to patient airways for diagnostic and therapeutic procedures. The Monarch Platform consists of three major components, (1) Monarch™ Endoscopy Cart, (2) Monarch™ Endoscopy Tower, and (3) Monarch™ Bronchoscope System, and working channel instruments.

The Monarch Cart provides support for the effector arms. It includes two robotic arms and the electronic systems required to power and operate the robotic system.

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. In addition, the tower includes an endoscopic controller that allows the user to control the system during a procedure.

The user controls the system with an endoscopic controller which transmits user inputs through the electromechanical system to the end effectors. The Monarch Bronchoscope System comprising of a bronchoscope and sheath is attached at the end effector of a robotic arm with multiple degrees of freedom. The flexible bronchoscope has a working channel and a camera at the tip. The bronchoscope has an articulated tip that can bend in all directions. The working channel of the bronchoscope is used for irrigation, aspiration and to deliver the working channel instruments.

The single-use manually controlled working channel instruments compatible with the Monarch Platform include the Aspirating Biopsy Needle, Biopsy Forceps, and Cytology Brush. All three have the same technological characteristics as the respective predicates and reference devices, that is, they are intended to operate in the same manner for collection of tissue or cells in the patient's lungs through a flexible endoscope or other working channel.

The Aspirating Biopsy Needle is comprised of a polymeric shaft with a needle joined to the distal end. A Luer fitting at the proximal end of the shaft allows the user to provide suction to the needle via the supplied syringe. A handle mechanism interfaces with the shaft to provide extension and retraction of the needle, and an outer jacket provides protection when the needle is not in use.

The Cytology Brush is comprised of an outer sheath and an inner catheter assembly. The inner catheter assembly consists of a thumb ring at the proximal end and a shaft to connect to the distal end which terminates in a brush. When the catheter is inserted into a working channel, the distal brush would be in a retracted position inside the outer sheath. When the catheter is in position, the brush can be extended into the tissue to obtain samples by advancing the proximal thumb ring.

The Biopsy Forceps instrument is comprised of a coil pipe with a mechanical jaw assembly joined to the distal end. The jaws are opened by sliding the outer handle component distally relative to the inner, longer handle component. The jaws are closed by squeezing the two components together.

## **V. INTENDED USE/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.

## **VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE AND REFERENCE DEVICE**

Overall, the Monarch Platform, Karl Storz Bronchoscope and ARES are based on the following similar basic technological elements:

- Device contains a flexible bronchoscope to visualize and gain access to the tracheobronchial tree.
- Device is intended for procedures performed by physician users via access through the bronchoscope working channel.
- Device requires continuous direct control by physician user to move the bronchoscope.
- Device moves the distal tip by pulling wires.
- Device enables use of working channel instruments to perform diagnostic and therapeutic procedures via working channel.
- Monarch Bronchoscope System is sterile.

The Karl Storz bronchoscope lacks the electro-mechanical control mechanism and navigation included with the Monarch Platform. For this reason, we are using the cleared ARES and SuperDimension Navigation System as reference devices. The cleared reference devices have been selected to address issues of safety and effectiveness for the differing technologies.

The Aspirating Biopsy Needle and the PeriFLEX Transbronchial Aspiration Needle have similar technological characteristics. Both devices operate in the same manner to obtain a tissue biopsy using a bronchoscope. The primary difference between the subject and predicate devices is the handle design. Other differences between the subject and predicate include the working outer diameter, needle protrusion length, needle tip material, needle gauge, and the working length. There are no differences that raise different questions of safety and effectiveness relative to the predicate.

The Biopsy Forceps and the Olympus FB series biopsy forceps have the same intended use with minor technological differences, namely the jaw diameter and the working length; and do not raise new or different questions of safety and effectiveness relative to the predicate.

The Cytology Brush and Wang Bronchial Needle Brush have the same intended use and minor technological characteristic differences, namely brush length, brush diameter and working length; and do not raise new or different questions of safety and effectiveness relative to the predicate.

## **VII. PERFORMANCE DATA**

The Monarch Platform has been subjected to and successfully tested for function, performance, and safety per FDA-recognized standards. In addition, the Monarch Platform has been evaluated for electrical safety and electromagnetic compatibility, biocompatibility and toxicity testing of patient-contacting materials. The following performance data was provided in support of the substantial equivalence determination.



### **Biocompatibility testing**

The biocompatibility evaluation for the direct and indirect body contacting components of the Monarch Platform - specifically the Monarch Bronchoscope System , working channel instruments, and accessories - was conducted in accordance with the FDA Blue Book Memorandum #95-1 “Use of International Standard ISO-10993, “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,” May 1, 1995, and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA.

The Ethylene Oxide sterilized devices were validated as biocompatible with the appropriate selection of tests indicated for Externally Communicating Devices, in contact with Tissue/Bone/Dentin, with limited contact duration (less than 24 hours). Tests included Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity and Material-Mediated Pyrogenicity.

The non-sterilized devices have been validated as biocompatible with the appropriate suite of biocompatibility tests indicated for Surface Devices, in contact with the Skin, with limited contact duration (less than 24 hours). Tests included Cytotoxicity, Sensitization, and Irritation.

### **Electrical safety and electromagnetic compatibility (EMC)**

Electrical safety and EMC testing were conducted on the Monarch Platform, consisting of the Monarch Tower, Monarch Cart, and Monarch Bronchoscope System. The system complies with the IEC 60601-1, and IEC 60601-2-18 standards for safety and the IEC 60601-1-2 standard for EMC.

### **Software Verification and Validation Testing**

Software verification and validation testing were conducted and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” issued May 11, 2005. Results of verification and validation testing confirm that the Monarch Platform conforms to design specifications and meets the needs of the intended users.

### **Monarch Platform Performance Testing**

- Monarch Cart
- Monarch Tower
- Robotic Arms and Instrument Device Manipulators
- Endoscopic Controller
- Vision
- Navigation
- Fluidics
- System Algorithms
- Bronchoscope and Sheath
- Working Channel Instruments and Accessories
- Simulated Use Testing

### **Aspirating Biopsy Needle Performance Testing**

- Puncture Force
- Insertability into Bronchoscope Working Channel Bronchoscope Deflection
- Positive/Negative Pressure and Leak Test
- Inadvertent Needle Deployment
- Minimum Needle Deployment
- Handle Assembly Strength and Durability
- Handle Actuation Torque and Force
- Nitinol Needle Buckling and Shear
- Catheter to Handle Joint Strength
- Nitinol Needle to Catheter Joint Strength
- Device Radiopacity
- Device Durability
- Gold Marker Adhesion
- Needle Targeting Accuracy
- Dimensional Testing
- Simulated Use
- Sterilization Validation
- Packaging and Shelf Life

### **Cytology Brush Performance Testing**

- Insertability into Bronchoscope Working Channel
- Bronchoscope Deflection
- Inadvertent Brush Deployment
- Minimum Brush Deployment
- Ability to Cut with Scissors
- Atraumatic Ball Retention Strength
- Handle Assembly Strength and Durability
- Catheter to Handle Joint Strength
- Brush Head to Catheter Joint Strength
- Device Radiopacity
- Device Durability
- Dimensional Testing
- Simulated Use
- Sterilization Validation
- Packaging and Shelf Life

### **Biopsy Forceps Performance Testing**

- Insertability into Bronchoscope Working Channel
- Bronchoscope Deflection
- Handle Assembly Strength and Durability
- Catheter to Handle Joint Strength
- Distal Assembly Strength
- Jaw Opening Angle

- Device Radiopacity
- Device Durability
- Dimensional Testing
- Simulated Use
- Sterilization Validation
- Packaging and Shelf Life

#### **Navigational Accuracy Comparative Study**

A comparative study of the ‘Navigation Yield’ and ‘Distance to Target’ metrics of the Medtronic/Covidien superDimension™ System (superDimension™) against the Monarch Platform was completed. The Monarch Platform Navigation System and superDimension™ System have substantially equivalent segmental, sub-segmental accuracy and on target accuracy, and thus equivalent Navigation Yield.

#### **Animal and Cadaver 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.

#### **Usability/Human Factors Testing**

Auris performed usability and human factors testing of the Monarch Platform. Simulated 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. The testing demonstrated that Monarch Platform design meets the intended user requirements and facilitates safe and effective user interactions with little chance of committing dangerous user errors.

## **VIII. CONCLUSION**

Based on the indications for use, technological characteristics, and performance testing, Auris has demonstrated that the Monarch Platform and Auris working channel instruments are as safe and effective as the predicate and reference devices for the stated intended use to collect tissue samples, and that the Monarch Platform and Auris’ working channel instruments are, as a result, substantially equivalent to the predicate devices.