DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 26, 2016

Auris Surgical Robotics, Inc.
% Mr. Michael Daniel
President, Daniel & Daniel Consulting, Llc
Daniel & Daniel Consulting, LLC
340 Jones Lane
Gardnerville, Nevada 89460

Re: K152319
Trade/Device Name: Auris Robotic Endoscopy System (ARES)
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible or Rigid) and Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: April 28, 2016
Received: April 29, 2016

Dear Mr. Daniel:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

6. Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(K) Number (if known)

K152319

Device Name

Auris Robotic Endoscopy System (ARES)

◦ Indications for Use *(Describe)*

The Auris Robotic Endoscopy System (ARES) is intended to provide bronchoscopic visualization of patient airways.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

FORM FDA 3881 (1/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

7. Premarket Notification 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: K152319

Applicant Information:

Date Prepared: May 26, 2016

Name:	Auris Surgical Robotics
Address:	125 Shoreway Road, Suite D San Carlos, CA 94070
Contact Person:	Michael A Daniel, Consultant madaniel@clinregconsult.com
Mobile Number:	(415) 407-0223
Office Number:	(775) 392-2970
Facsimile Number:	(610) 545-0799
Company Contact:	Joy Sacmar, VP RA/QA, Auris Surgical Robotics joy.sacmar@aurisrobotics.com

Device Information:

Device Trade Name:	Auris Robotic Endoscopy System (ARES)
Common Name:	Bronchoscope (Flexible) and Accessories
Classification Name(s):	Bronchoscope (Flexible) and Accessories
Product Code/ Regulation:	EOQ 21 CFR 874.4680
Classification:	Class II

Predicate Device:

- Karl Storz Video Bronchoscope System – K071530

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

Reference Devices:

- Olympus Bronchoscope – K121959
- Hansen Medical catheter articulation system – K052480

Device Description:

The Auris Robotic Endoscopy System (ARES) is intended to be used by qualified physicians to provide visualization to the Bronchial Tree during Bronchoscopic procedures. The ARES consists of four major components, (1) the Patient Side System (PSS), (2) Controller Cart, (3)

Surgeon Console (also known as the Master Device Workstation) and (4) the Bronchoscope and Accessories.

The Patient Side System (PSS) includes the robot cart, two robot arms, both Endoscope and Sheath IDMs, IDS, servo drives box, Endoscope camera control box, power control box, illumination controller, and necessary cabling between the IDM/IDS and the robot cart.

The Controller Cart houses the electronic systems required to power and operate the robotic systems. The Controller Cart is broken into two smaller carts, the system controller cart, and the arm controller cart.

The Master Device Workstation is the workstation from which the surgeon drives the ARES. The console consists of a pendant that allows the surgeon to control various aspects of the system during a procedure.

The system is based on a master – slave model, where the user (i.e. physician) is controlling the robots (slaves) using a pendant (master). The flexible bronchoscope 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 four directions. The working channel of the Bronchoscope is used for irrigation and aspiration.

Each Slave includes a robotic arm with 6 degrees of freedom and an IDM (Instrument Drive Mechanism) with 4 actuated axes. The robotic arms are used to steer the Bronchoscope.

Indications for Use:

The Auris Robotic Endoscopy System (ARES) is intended to provide bronchoscopic visualization of patient airways.

Comparison to Predicate and Reference Devices

The tables on the following pages provide a summary of substantial equivalence between the subject device and the cited predicate as well as the similarity between the subject device and the chosen reference device. The subject device has the same intended use and substantially equivalent technological characteristics that do not raise different questions of safety or effectiveness.

Comparison to Predicate and Reference Devices:

Key Attributes	Subject Device	Predicate Device	Reference Device 1	Reference Device 2
	ARES System (electromechanical control system plus integrated Bronchscope)	Karl Storz Bronchoscope	Olympus Bronchoscope	Hansen Medical Catheter and Control System
K Number	K152319	K071530	K121959	K052480
Indication for Use	The Auris Robotic Endoscopy System (ARES) is intended to provide bronchoscopic visualization of patient airways.	The Karl Storz Video Bronchoscope System is intended for use by physicians for diagnostic and therapeutic procedures in nasal, sinus and nasopharyngeal endoscopy, bronchoscopy, tracheoscopy and esophagoscopy and laryngoscopy. The Karl Storz; Video Bronchoscope is intended to provide visualization via a video monitor.	These instruments have been designed to be used with an Olympus video system center, light source, documentation equipment, video monitor, endo-therapy accessories (such as biopsy forceps) and other ancillary equipment for endoscopy and endoscopic surgery within the airways and tracheobronchial tree.	The Hansen Medical Catheter Control System, Steerable Guide Catheter, Sheath, and accessories are intended to facilitate manipulation, positioning and control, for collecting electrophysiological data within the heart atria with electro-anatomic mapping and recording systems, using the following percutaneous mapping catheters...
Method of Distal tip movement	Pull Wires	Pull Wires	Pull Wires	Pull Wires
Method of pulling pull wires	Electromechanical (servo/stepper motors + software)	Mechanical linkage to handle (no electromechanics)	Mechanical linkage to handle (no electromechanics)	Electromechanical (servo/stepper motors + software)
Control / Physician interface	Joysticks and buttons on pendant controller	Thumb and finger wheels on handle	Thumb and finger wheels on handle	Joysticks and buttons on pendant controller?
Bronchoscope Dimensions and optical attributes	Reference Bronchoscope Comparison Chart below			N/A

Scope	Channel I.D.	Scope O.D.	Working Length
Olympus BF-Q190	2.0 mm	4.8 mm	60 cm
Olympus EVIS Exera (BF-3C160)	1.2 mm	3.8 mm	60 cm
Olympus Exera (BF-MP160F)	2.0 mm	4.0 mm	600 mm
Olympus Diagnostic (BF-XP190)	1.2 mm	3.1 mm	600 mm
Storz Broncho-fiberscope (11003)	1.2 mm	2.8 mm	N.S.

Testing Completed:

Preclinical testing included standard bench or *in vitro* testing confirming functionality and durability (e.g., tensile and other durability and functional evaluation). The Porcine animal model was used to validate system performance *in vivo*.

Verification and validation testing was completed in compliance with the following standards:

- IEC 60601-1:2005 + CORP. 1 (2006) + CORP. 2 (2007) + AM1 (2012) or IEC 60601-1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD).
- IEC/EN 60601-1-2:2007/AC:2010, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3). FDA recognition number: 19-2
- IEC 60601-2-18 Edition 3.0 2009-08, Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment. FDA recognition number: 9-61
- ISO 10993-1:2009(R) 2013, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (Biocompatibility). FDA recognition number: 2-156
- ISO 10993-5: 2009/(R) 2014, Biological evaluation of medical devices - part 5: tests for in vitro cytotoxicity. (Biocompatibility). FDA recognition number: 2-153
- ISO 10993-6: 2007/(R) 2010, Biological evaluation of medical devices - part 6: tests for local effects after implantation (Biocompatibility). FDA recognition number: 2-120
- ISO 10993-10: 2010, Biological evaluation of medical devices-part 10: tests for irritation and skin sensitization. (Biocompatibility). FDA recognition number: 2-173
- ISO 10993-11: 2006/(R)2010, Biological evaluation of medical devices-part 11: tests for systemic toxicity. (Biocompatibility). FDA recognition number: 2-118

- ISO 14971:2012, Medical devices – application of risk management to medical devices. FDA recognition number: 5-40
- ISO 14937:2009, Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation, and routine control of a sterilization process for medical devices. FDA recognition number: 14-291
- ISO 11137-2:2013, Sterilization of health care products – radiation- Part 2: Establishing the sterilization dose. FDA recognition number: 14-409
- ANSI/AAMI ST81:2004 (R)2010, Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices. FDA recognition number: 14-295
- ANSI/AAMI ST79:2010, Comprehensive guide to steam sterilization and sterility assurance in health care facilities. FDA recognition number: 14-439
- ISO 8600-3 First Edition 1997, Optics and Optical instruments - Medical endoscopes and endoscopic accessories - Part 3: Determination of field of view and direction of view of endoscopes with optics [Including: Amendment 1 (2003)]. FDA recognition number: 9-84

Testing described in this 510(k) consisted of verification of all design input requirements and product specifications. All clinical input requirements were validated.

Summary:

Based upon the Intended Use, product technical information, performance evaluation, and standards compliance provided in this premarket notification, the Auris Robotic Endoscopy System (ARES), has been shown to be substantially equivalent to the cited predicates and very similar to the cited reference device.