February 14, 2019

Intuitive Surgical
Sarah Rizk
Sr. Regulatory Engineer
1266 Kifer Road
Sunnyvale, CA 94086

Re: K182188
Trade/Device Name: Ion Endoluminal System; Flexision Biopsy Needle
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: January 14, 2019
Received: January 15, 2019

Dear Sarah Rizk:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely yours,

Srinivas Nandkumar -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

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)*
K182188

Device Name
Ion™ Endoluminal System (Model IF1000)

Indications for Use *(Describe)*
The Ion™ Endoluminal System (Model IF1000) assists the user in navigating a catheter and endoscopic tools in the pulmonary tract using endoscopic visualization of the tracheobronchial tree for diagnostic and therapeutic procedures. The Ion™ Endoluminal System enables fiducial marker placement. It does not make a diagnosis and is not for pediatric use.

The Flexision™ Biopsy Needle is used with the Ion™ Endoluminal System to biopsy tissue from a target area in the lung.

The PlanPoint™ Software uses patient CT scans to create a 3D plan of the lung and navigation pathways for use with the Ion™ Endoluminal System.

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)

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510(K) SUMMARY

1. SUBMITTER

510(k) Owner: Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, CA 94086

Contact: Sarah Rizk
Senior Regulatory Engineer
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Date Prepared: August 10, 2018

2. DEVICE AND PREDICATE/REFERENCE DEVICES

Trade Name:	Ion™ Endoluminal System
Common Name:	Bronchoscope (flexible or rigid) and accessories
Classification:	Class II 21 CFR 874.4680 Bronchoscope (flexible or rigid) and accessories
Product Codes:	EOQ
Advisory Committee:	Ear, Nose, and Throat
Predicate Devices:	Schoelly Video Bronchoscope (K141366)

Trade Name:	Flexision™ Biopsy Needle
Common Name:	Bronchoscope (flexible or rigid) and accessories
Classification:	Class II 21 CFR 874.4680 Bronchoscope (flexible or rigid) and accessories
Product Codes:	EOQ
Advisory Committee:	Ear, Nose, and Throat
Predicate Devices:	Arcpoint Pulmonary Needle (K163537)

In compliance with FDA Guidance "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]", Intuitive Surgical also included the following as reference devices:

Trade Name: Monarch Endoscopy Platform

510(k) Number:	K173760
Manufacturer:	Auris Surgical Robotics, Inc.

Trade Name:	superDimension™ Navigation System
510(k) Number:	K173244
Manufacturer:	Covidien, LLC

3. DEVICE DESCRIPTION

The Ion™ Endoluminal System, Model IF1000, is a software-controlled, electro-mechanical system designed to assist qualified physicians to navigate a catheter and endoscopic tools in the pulmonary tract using endoscopic visualization of the tracheobronchial tree for diagnostic and therapeutic procedures. It consists of a Planning Laptop with PlanPoint™ Software, a System Cart with System Software, a Controller, Instruments, and Accessories. The IF1000 Instruments include the Ion™ Fully Articulating Catheter, the Ion™ Peripheral Vision Probe, and the Flexision™ Biopsy Needles.

The Planning Laptop is a separate computer from the System Cart and Controller. A 3D airway model is generated from the patient's chest CT scan using the PlanPoint™ Software.

The System Cart contains the Instrument Arm, electronics for the slave portion of the servomechanism, and two monitors. The System Cart allows the user to navigate the Catheter Instrument with the Controller, which represents the master in the master/slave relationship. For optimal viewing, the physician can position the monitors in both vertical and horizontal axes.

The Controller is the user input device on the Ion™ Endoluminal System. It provides the controls to command insertion, retraction, and articulation of the Catheter. The Controller also has buttons to operate the Catheter control states.

The Catheter Instrument has a tool channel compatible with the Peripheral Vision Probe, Flexision™ Biopsy Needles, and third-party tools. The Vision Probe provides direct visualization of the patient's airways during navigation. Accessories such as the Catheter Guide, Vision Probe Adapter, Suction Adapter, and Swivel Connector facilitate use of the IF1000 Instruments.

4. INTENDED USE/INDICATIONS FOR USE

Intended Use

To provide access to and visualization of patient airways.

Indications for Use

The Ion™ Endoluminal System (Model IF1000) assists the user in navigating a catheter and endoscopic tools in the pulmonary tract using endoscopic visualization of the tracheobronchial tree for diagnostic and therapeutic procedures. The Ion™ Endoluminal System enables fiducial marker placement. It does not make a diagnosis and is not for pediatric use.

The Flexision™ Biopsy Needle is used with the Ion™ Endoluminal System to biopsy tissue from a target area in the lung.

The PlanPoint™ Software uses patient CT scans to create a 3D plan of the lung and navigation pathways for use with the Ion™ Endoluminal System.

5. TECHNOLOGICAL CHARACTERISTICS

The subject Ion™ Endoluminal System, Model IF1000, and the predicate Schoelly Video Bronchoscope (K141366) are similar in terms of technological characteristics and have fundamentally the same indications for use. Like the Schoelly Video Bronchoscope, the IF1000 System is designed for use in performing bronchoscopy biopsy procedures. Similar technological characteristics include the ability to provide direct visualization of the anatomy, a working channel for endoscopic instruments, and suctioning with a suction adapter accessory. The IF1000 System utilizes electromechanical controls for manipulating the Catheter tip, while the predicate device utilizes solely mechanical controls for manipulating the end of the bronchoscope. Table 1 provides a device comparison between the subject Ion™ Endoluminal System, Model IF1000, and the predicate Schoelly Video Bronchoscope (K141366).

Table 1: Ion™ Endoluminal System Comparison to Schoelly Video Bronchoscope System

Attribute	Subject Device Ion™ Endoluminal System	Predicate Device Schoelly Video Bronchoscope System (K141366)

Attribute	Subject Device **Ion™ Endoluminal System**	Predicate Device **Schoelly Video Bronchoscope System (K141366)**
Device Types	System Cart with Instrument Arm Controller Planning Laptop with PlanPoint™ Software Ion™ Fully Articulating Catheter Ion™ Peripheral Vision Probe Vision Probe Adapter Suction Adapter Catheter Guide Swivel Connector Reprocessing accessory kits (includes leakage tester)	Video bronchoscope Camera Control Unit Accessories Suction valve/seal accessory Leakage tester and reprocessing accessories
Intended Use	To provide visualization of patient airways.	**SAME** as subject device
Indications for Use	The Ion™ Endoluminal System assists the user in navigating a catheter and endoscopic tools in the pulmonary tract using endoscopic visualization of the tracheobronchial tree for diagnostic and therapeutic procedures. The Ion™ Endoluminal System enables fiducial marker placement. It does not make a diagnosis and is not for pediatric use.	The Schoelly Video Bronchoscope System is intended for use by physicians for diagnostic and therapeutic procedures in nasopharyngeal endoscopy, bronchoscopy, tracheoscopy, and laryngoscopy. The Schoelly Video Bronchoscope is intended to provide visualization via a video monitor.
Principles of Operation	Visualization of endoluminal spaces via light delivery and video Navigation through endoluminal spaces via tip deflection capabilities Provides a working channel through which other instruments can be delivered to target sites within the airways	**SAME** as subject device
Tip	Steerable distal tip for control and manipulation within discrete regions of the lung.	**SAME** as subject device
Method of Distal Tip Movement	Electromechanically (servo/stepper motors and software) controlled pull wires.	Manually controlled pull wires.
Steering Method	Robotic master/slave control system with servo motor/encoder and cable interface.	Joy stick on handle.
Tool Channel Diameter	2 mm	2.2 mm

Attribute	Subject Device Ion™ Endoluminal System	Predicate Device Schoelly Video Bronchoscope System (K141366)
Articulation Range	180^0 in all four directions (pitch and yaw)	Up 210^0/ down 130^0
Illumination Source	Light-emitting diodes.	**SAME** as subject device
Field of View	90°	120°
Direction of View	0^0	**SAME** as subject device
Imaging Sensor	CMOS Imaging Sensor	**SAME** as subject device
Duration of Visualization	During navigation of Catheter Instrument, up to the biopsy location.	During navigation of bronchoscope and biopsy.
Guided Navigation	3D guided navigation view on System Cart.	None
Location Sensing	Located in Catheter Instrument, during navigation and biopsy.	None
Procedure Planning	PlanPoint™ Software converts DICOM CT scan data into segmented 3D lung model.	None
Registration	System directs user to drive Catheter Instrument for registration	None
Patient Contact Materials	Stainless Steel Silicone Pellethane plastic PTFE plastic Glass Polyamide resin Pebax elastomer (TPE) Polyamide	PEEK Polyurethane PTFE plastic Fused silica Polyphenylsulfone Fiber glass Rubber

The subject Flexision™ Biopsy Needle and the predicate Arcpoint Pulmonary Needle, Models ILS-1800-PN and ILS-2100-PN, are similar in terms of technological characteristics and have fundamentally same indications for use. Like the Arcpoint Pulmonary Needle, the Flexision™ Biopsy Needle is designed for retrieving tissue from a target site in the lung. Both the subject and predicate devices use similar means to collect tissue biopsy samples, compatible with the same-sized working channels, and have similar tip geometry. The subject Flexision™ Biopsy Needle differs in needle protrusion length and needle gauge sizes offered. Table 2 provides a device comparison between the subject Flexision™ Biopsy Needle and the predicate Arcpoint Pulmonary Needle (K163537).

Table 2: Flexision™ Biopsy Needle Comparison to Arcpoint Pulmonary Needle (K163537)

Attribute	Subject Device Flexision™ Biopsy Needle	Predicate Device Arcpoint Pulmonary Needle (K163537)
Intended Use	To retrieve tissue from a target structure.	**SAME** as subject device
Principles of Operation	Captures sample of tissue for subsequent diagnosis.	**SAME** as subject device
Indications for Use	The Flexision™ Biopsy Needle is used with the Ion™ Endoluminal System to biopsy tissue from a target area in the lung.	The Arcpoint pulmonary needle is utilized through a flexible endoscope or with the superDimension Navigation System by physicians who are trained for retrieving specimens from patients with endobronchial lesions, peripheral lung nodules or lung masses.
Anatomical Site	Lung	**SAME** as subject device
Method of Introduction	Endobronchial, delivered to the target through the Fully Articulating Catheter.	**SAME** as subject device, delivered to the target through a flexible endoscope or superDimension System Extended Working Channel.
Sample Collection	Aspiration with a syringe.	**SAME** as subject device
Sizes	23G, 21G, and 19G	21G and 18G
Required Working Channel	2 mm	**SAME** as subject device
Needle Tip	Sharp, beveled	**SAME** as subject device
Protrusion Length	1- 3 cm	8 mm
Shaft Marks	Yes	**SAME** as subject device
Stylet	Yes	**SAME** as subject device
Radiopaque Distal End	Yes	**SAME** as subject device
Life/Sterility	Single use, EtO sterilized	**SAME** as subject device
Patient Contact Materials	Polyamide Pebax Stainless Steel	Copolyester elastomer polymer Stainless Steel

Results of verification and validation testing demonstrate that the subject devices are equivalent to the predicate devices in terms of safety and effectiveness. Furthermore, the testing did not raise any new risks and did not raise any new safety or effectiveness questions for the subject devices.

6. PERFORMANCE DATA

Performance testing data (bench, animal, and cadaver tests) demonstrate that the subject device is substantially equivalent to the predicate devices and that the design output meets the design input requirements. The testing included dimensional measurements, mechanical verification, functional verification, reliability testing, electrical safety, electromagnetic compatibility (EMC), biocompatibility of patient-contacting materials, software verification and validation, and simulated use in animals and cadavers.

Biocompatibility Testing

The patient-contacting components of the Ion™ Endoluminal System, IF1000, are classified in accordance with ISO 10993-1 as external communicating, blood path indirect, with limited contact duration (≤24 hrs). The biocompatibility evaluation of patient-contacting components was conducted in accordance with the following guidance and standard:

- FDA Guidance: "Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process," June 2016
- ISO 10993-1: Biological evaluation of medical devices

All direct and indirect patient-contacting components of the Ion™ Endoluminal System underwent cytotoxicity, intracutaneous irritation, sensitization and/or acute systemic toxicity testing in accordance to ISO 10993-5, ISO 10993-10 and ISO 10993-11. Biocompatibility testing was performed by a third party laboratory in compliance with Good Laboratory Practices (GLP).

Reprocessing/Sterilization/Packaging/Shelf Life Testing

Cleaning, disinfection, sterilization, and packaging/shelf life testing was conducted for the Ion™ Endoluminal System (IF1000) subsystems, Instruments, and Accessories. Testing was performed in accordance with the following standards and guidances:

- AAMI TIR30: 2011 A Compendium Of Processes, Materials, Test Methods, And Acceptance Criteria For Cleaning Reusable Medical Devices
- AAMI TIR12:2010: Technical Information Report - Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for device manufacturers
- AAMI/ANSI/ISO 17665-1:2006 /(R)2013: Sterilization of health care products – Moist heat Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
- AAMI/ANSI ST79:2017: Comprehensive guide to steam sterilization and sterility assurance in health care facilities

- ANSI/AAMI/ISO 11135:2014: Sterilization of health care products – Ethylene oxide — Requirements for development, validation and routine control of a sterilization process for medical devices
- ISO 10993-7:2008/(R)2012: Biological evaluation of medical devices – Part 7 – Ethylene oxide sterilization residuals
- ANSI/AAMI/ISO 11737-1:2006/(R)2011: Sterilization of health care products – Microbiological methods—Part 1: Determination of the population of microorganisms on product
- ANSI/AAMI/ISO 11737-2:2009/(R)2014: Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- AAMI TIR28:2009 Product Adoption and Process Equivalence for Ethylene Oxide Sterilization
- FDA Guidance: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (March 17, 2015)
- FDA Guidance: Submission and Review of Sterility Information in Pre-Market Notification 510(k) Submissions for Device Labeled as Sterile (January 21, 2016)
- AAMI ST72:2011/(R)2016 Bacterial Endotoxins - Test Methods, Routine Monitoring, And Alternatives To Batch Testing
- FDA Guidance: Pyrogen and Endotoxins Testing: Questions and Answer (June 2012)
- ASTM D4169:2016: Standard Practice for Performance Testing of Shipping Containers and Systems
- ISO 11607-1: 2006/Am1:2014: Packaging for terminally sterilized medical devices, Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ASTM F88/F88M:2015: Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM D4332:2014: Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing
- ASTM F1980:2016: Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Device
- ASTM F1140/F1140M-13: Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages

EMC and Electrical Safety Testing

The Ion™ Endoluminal System was tested for electrical safety and EMC, including co-existence testing, and complies with IEC 60601-1, IEC 60601-2-18, and IEC 60601-1-2.

Software Verification and Validation

Software for the Ion™ Endoluminal System underwent software verification and validation testing and results demonstrate that the System meets design specifications and user needs. Software documentation has been provided according to 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.

Bench Testing

The Ion™ Endoluminal System, Instruments, and Accessories were subjected to full design verification. A summary of the design verification testing for the System Cart and the Controller is listed below:

Component	Testing
System Cart	Bench testing was performed in order to confirm that the design outputs for the System Cart met the design input requirements. Testing was also performed to confirm that the requirements regarding EMC, electrical safety, software, and disinfection had been met.
Controller	Bench testing was performed in order to confirm that the design outputs for the Controller met the design input requirements. Testing was also performed to confirm that the requirements regarding EMC, electrical safety, software, and disinfection had been met.

The Planning Station and PlanPoint™ Software were subjected to full design verification. A summary of the design verification testing for the Planning Station is listed below:

Component	Testing
Planning Station	Bench testing was performed in order to confirm that the design outputs for the Planning Station met the design input requirements. Testing was also performed to confirm that the requirements regarding software had been met.

Testing was performed on each instrument type to verify that the design meets physical, mechanical, user interface, and equipment interface requirements. A summary of the design verification testing for the IF1000 Instruments is described below:

Component	Testing
Fully Articulating Catheter	Verification testing was performed to evaluate design specifications such as physical, mechanical, electrical, and equipment interface requirements. Testing was also performed to confirm that the requirements regarding biocompatibility, packaging, cleaning, disinfection validation, and use life had been met.
Peripheral Vision Probe	Verification testing was performed to evaluate design specifications such as physical, mechanical, electrical, and equipment interface requirements. A Modulation Transfer Function Analysis was performed to characterize the Vision Probe's optical performance. Testing was also performed to confirm that the requirements regarding biocompatibility, packaging, cleaning, disinfection validation, and use life had been met.

Flexision™ Biopsy Needles	Verification testing was performed to evaluate design specifications such as physical, mechanical, electrical, and equipment interface requirements. Testing was also performed to confirm that the requirements regarding biocompatibility, packaging, and sterilization validation had been met.

A summary of the design verification testing for the IF1000 Accessories is described below:

Component	Testing
Catheter Guide	Verification testing was performed to evaluate design specifications such as physical, mechanical, electrical, and equipment interface requirements. Testing was also performed to confirm that the requirements regarding biocompatibility, packaging, cleaning, sterilization validation, and use life had been met.
Vision Adapter **Suction Adapter** **Swivel Connector**	Verification testing was performed to evaluate design specifications such as physical, mechanical, electrical, and equipment interface requirements. Testing was also performed to confirm that the requirements regarding biocompatibility, packaging, and sterilization validation.

Animal and Cadaver Testing

Animal and cadaver testing was performed under simulated use conditions to evaluate safety or performance of the Ion™ Endoluminal System according to its intended use. Cadavers were used to demonstrate clinical performance for anatomical access and reach within the human lung anatomy. Live animal models were used to assess safety, performance and accuracy in cases where a living tissue model was appropriate. These models replicate factors experienced during clinical use, including working with respiration, bleeding, and normal tissue handling. Animal and cadaver testing demonstrated the Ion™ Endoluminal System can be used safely and effectively according to its intended use with no new risks identified.

Human Factors Evaluation

A human factors (HF) engineering process was followed in accordance with the following:

- ANSI/AAMI/IEC 62366-1:2015, Medical devices - Application of usability engineering to medical devices
- FDA Guidance: "Applying Human Factors and Usability Engineering to Medical Devices - Guidance for Industry and Food and Drug Administration Staff," 2016

A summative validation study was conducted to evaluate high-risk use scenarios and essential tasks that were not assessed in previous usability validations. This study was conducted by intended user groups in a simulated bronchoscopy suite and involved preoperative preparation and simulated procedures, as well as emergency procedures that involved safety-critical tasks. Training materials and user manuals were developed in concert with the product hardware and software, and were assessed in the validation study.

The Ion™ Endoluminal System has been assessed and found to be safe and effective for its intended use, by the intended users, in its intended use environment.

7. CONCLUSION

Based on the intended use, indications for use, technological characteristics and performance testing, the Ion™ Endoluminal System and the Flexision™ Biospy Needle are substantially equivalent (SE) to the predicate devices. This SE determination is based on bench testing including reliability testing, animal/cadaver validation, simulated clinical procedures in live animals, and human factors assessment. The bench/reliability testing verified that the design requirements and specifications have been met. The animal/cadaver validation provided clinical validation that the system can be used to safely and effectively complete the procedures encompassed by the indications for use statement. Finally, the human factors assessment provided further assurance that risks due to user errors have been identified and mitigated.