November 26, 2019

Intuitive Surgical, Inc.
Jennifer Siu
Sr. Regulatory Affairs Specialist
1266 Kifer Rd.
Sunnyvale, California 94086

Re: K192367
Trade/Device Name: Ion Endoluminal System
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible or Rigid) and Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: August 29, 2019
Received: August 30, 2019

Dear Jennifer Siu:

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 Mike Ryan
Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192367

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)

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

1. Submitter

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

Contact: Jennifer Siu
Senior Regulatory Affairs Specialist
Tel: (408) 523-5372
Email: jennifer.siu@intusurg.com

Date of Submission: August 29, 2019

2. Device Information

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 Code:	EOQ
Review Panel:	Ear, Nose, and Throat

3. Predicate Device

The predicate device for this submission is the Ion™ Endoluminal System (K182188), cleared on February 14, 2019.

4. Device Description

The Ion™ Endoluminal System (Model IF1000) is a software-controlled, electromechanical 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 Model IF1000 Instruments include the Ion™ Fully Articulating Catheter, the Ion™ Peripheral Vision Probe, and the Flexision™ Biopsy Needles. Accessories such as the Catheter Guide, Vision Probe Adapter, Suction Adapter, and Swivel Connector facilitate use of the Model IF1000 Instruments.

5. 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.

6. Comparison to Predicate Device

The Model IF1000 Instruments, specifically the Ion™ Fully Articulating Catheter (Catheter) and the Ion™ Peripheral Vision Probe (Vision Probe), subject to the scope of change under this submission, remain substantially equivalent to the Model IF1000 Instruments cleared under K182188. There were no design changes made to the subject device as a result of the alternative microbicidal method.

Intuitive is providing an alternative microbicidal method for the reprocessing of the Catheter and Vision Probe instruments, to allow users the choice for these instruments to be reprocessed via an automated microbicidal process instead of the current manual microbicidal process. There are no changes to the subject device compared to the predicate device with regard to indications for use, technological characteristics, device materials, clinical utility, or packaging as a result of the alternative automated microbicidal process. **Table 1** provides a comparison between the subject device and predicate device.

Table 1. Comparison of Predicate and Subject Devices

	Predicate Device: Model IF1000 Catheter & Vision Probe (K182188)	**Subject Device: Model IF1000 Catheter & Vision Probe (This Submission)**
FDA Product Code	EOQ	SAME as predicate
Classification	Class II - 21 CFR §874.4680	SAME as predicate
Classification Name	Bronchoscope (flexible or rigid) and accessories	SAME as predicate

	Predicate Device: Model IF1000 Catheter & Vision Probe (K182188)	Subject Device: Model IF1000 Catheter & Vision Probe (This Submission)
Intended Use	To provide visualization of patient airways	SAME as predicate
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	SAME as predicate
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 predicate
Method of Distal Tip Movement	Electromechanically (servo/stepper motors and software) controlled pull wires	SAME as predicate
Tool Channel Diameter	2 mm	SAME as predicate
Patient Contact Materials	Stainless Steel Silicone Pellethane plastic PTFE plastic Glass Polyamide resin Pebax elastomer (TPE) Polyamide	SAME as predicate
Reusable	Yes	SAME as predicate
Requires Reprocessing	Yes	SAME as predicate
Reprocessing - Microbicidal Method	Manual microbicidal process	Manual microbicidal process or Automated microbicidal process

Verification and validation testing results demonstrate that the subject device reprocessed via the automated microbicidal process is substantially equivalent to the predicate device

reprocessed via the manual microbicidal process. Furthermore, the testing did not raise any new risks or any new questions in terms of safety and effectiveness for the subject device.

7. Performance Data

The following performance data has been provided in support of the substantial equivalence determination. Testing included reprocessing, biocompatibility, bench testing, and usability testing.

Reprocessing Validation

3 automated reprocessing equipment were validated to support the automated microbicidal process of the Catheter and Vision Probe, to demonstrate the efficacy of the automated reprocessing equipment in disinfecting/sterilizing the Model IF1000 devices. Testing was performed in accordance with AAMI TIR12:2010 *Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers*. All testing passed the predetermined acceptance criteria.

Biocompatibility

In order to assess the biological responses to patient contact of the Catheter and Vision Probe from chemical residuals used during the automated microbicidal process, Cytotoxicity testing was performed. Testing was performed on the Model IF1000 devices subjected to each representative automated reprocessing equipment in accordance with ISO 10993-5:2009 *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity*. All testing passed the predetermined acceptance criteria.

Bench Testing

A series of bench testing was performed to verify and validate that the Model IF1000 devices continue to meet the existing functional requirements following the automated microbicidal process. The series of testing is outlined below. All testing passed the predetermined acceptance criteria.

Performance Bench Test Results	
Test	**Conclusion**
Design Verification Testing for Catheter	Pass
Design Verification Testing for Vision Probe	Pass
Reliability Testing for Catheter	Pass
Reliability Testing for Vision Probe	Pass

Usability Testing

A human factors study was performed to validate the additional instructions added to support the alternative automated microbicidal process. The study was conducted in accordance with FDA guidances *Applying Human Factors and Usability Engineering to Medical Devices*, issued February 3, 2016, and *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*, issued March 17, 2015. The study demonstrates the intended users can successfully understand and perform the intended reprocessing procedure

safely and effectively while following the reprocessing instructions manuals, and therefore successfully validates the added instructions.

Animal Testing
No animal studies were performed as appropriate verification and validation for the subject device were achieved in accordance with the acceptance criteria for the predicate device and from the results of the bench and usability testing.

Clinical Testing
No clinical studies were performed as appropriate verification and validation for the subject device were achieved in accordance with the acceptance criteria for the predicate device and from the results of the bench and usability testing.

8. Conclusion

Based upon the intended use, design, operating principles, comparison to the predicate device, and conducted testing, it is concluded that the subject device reprocessed via an automated microbicidal process is substantially equivalent to the predicate device reprocessed via a manual microbicidal process. Testing also supports that the subject device reprocessed via an automated microbicidal process does not raise any new risks or any new questions in safety or effectiveness compared to the predicate device.