August 26, 2021

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

Re: K212048
Trade/Device Name: Ion Endoluminal System (Ion Fully Articulating Catheter), Ion Endoluminal System (Ion Peripheral Vision Probe)
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: June 28, 2021
Received: June 30, 2021

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,

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1C: 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)*
K212048

Device Name
Ion™ Endoluminal System (Ion™ Fully Articulating Catheter) (IF1000);
Ion™ Endoluminal System (Ion™ Peripheral Vision Probe) (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.

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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: June 28, 2021

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 (K201146), cleared on June 26, 2020.

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, Swivel Connector, and Vision Probe Bag 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 K201146. There were no design changes made to the subject devices as a result of the alternative automated cleaning process and reduced rinsing steps of the existing manual cleaning process.

Intuitive is providing an alternative cleaning method and reducing rinsing steps for the current manual cleaning 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 cleaning process and simplify the current manual cleaning process. There are no changes to the subject devices compared to the predicate devices with regard to indications for use, technological characteristics, device materials, clinical utility, or packaging as a result of the alternative automated cleaning process or reduced rinsing steps of the existing manual cleaning process. **Table 1** provides a comparison between the subject devices and predicate devices.

Table 1. Comparison of Predicate and Subject Devices

	Predicate Device: Model IF1000 Catheter & Vision Probe (K201146)	**Subject Device: Model IF1000 Catheter & Vision Probe (This Submission)**
FDA Product Code	EOQ	SAME as predicate

	Predicate Device: Model IF1000 Catheter & Vision Probe (K201146)	**Subject Device: Model IF1000 Catheter & Vision Probe (This Submission)**
Classification	Class II - 21 CFR §874.4680	SAME as predicate
Classification Name	Bronchoscope (flexible or rigid) and accessories	SAME as predicate
Intended Use	To provide access to and 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 Catheter Distal Tip Movement	Electromechanically (servo/stepper motors and software) controlled pull wires	SAME as predicate
Catheter Tool Channel Diameter	2 mm	SAME as predicate
Vision Probe Illuminating Source	Light emitting diodes	SAME as predicate
Vision Probe Direction of View	0°	SAME as predicate
Vision Probe Field of View*	90°	120°
Patient Contact Materials*	Stainless Steel Silicone Pellethane plastic PTFE plastic Glass Polyamide resin Pebax elastomer (TPE) Polyamide Cyanoacrylate	Similar to predicate

	Predicate Device: Model IF1000 Catheter & Vision Probe (K201146)	**Subject Device: Model IF1000 Catheter & Vision Probe (This Submission)**
Reusable	Yes	SAME as predicate
Requires Reprocessing	Yes	SAME as predicate
Reprocessing Method	Manual cleaning and manual microbicidal process or Manual cleaning and automated microbicidal process	Manual cleaning and manual microbicidal process or Manual cleaning and automated microbicidal process or Automated cleaning and automated microbicidal process

* Note: The Vision Probe's field of view has increased from 90° to 120° for a better view during instrument navigation with minor material changes that do not introduce any new or increased biological risk since clearance of the predicate device under K201146.

Cleaning validation results demonstrate that the subject devices reprocessed via the automated cleaning process and reduced rinsing steps of the existing manual cleaning process are substantially equivalent to the predicate devices reprocessed via the current manual cleaning process. Furthermore, the testing did not raise any new risks or any new questions in terms of safety and effectiveness for the subject devices.

7. Performance Data

The following performance data has been provided in support of the substantial equivalence determination. Testing included reprocessing validation, toxicological risk assessment, and usability testing.

Reprocessing Validation

Automated endoscope reprocessor (AER) equipment were validated to support the automated cleaning process of the Catheter and Vision Probe, to demonstrate the efficacy of the AERs in cleaning 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* and AAMI TIR30:2011/(R)2016 *A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices*. All testing passed the predetermined acceptance criteria.

Biocompatibility

In order to assess the biological risk to patient contact of the Catheter and Vision Probe from chemical residuals left following the automated cleaning process or reduced rinsing of the existing manual cleaning process, total organic carbon (TOC) testing were performed and evaluated. Testing were performed on the Model IF1000 devices subjected to the automated cleaning process and reduced rinsing of the existing manual process and results analyzed in

accordance with ISO 10993-1:2018 *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*. All testing were deemed to result in acceptable TOC levels, comparable to the predicate devices.

Bench Testing
No bench testing was performed as the automated cleaning process and reduced rinsing steps of the existing manual cleaning process do not introduce harsher reprocessing chemical or additional mechanical wear to the subject devices requiring additional verification and validation.

Usability Testing
A human factors study was performed to validate the additional instructions added to support the reprocessing instructions manuals updates subject of this submission. The study was conducted in accordance with FDA guidance *Applying Human Factors and Usability Engineering to Medical Devices*, issued February 3, 2016, and IEC 62366-1:2015/ Amd1:2020 *Medical devices – Part 1: Application of usability engineering to medical devices*. The study demonstrates that 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 updated instructions.

Animal Testing
No animal studies were performed as the automated cleaning process and reduced rinsing steps of the existing manual cleaning process do not introduce harsher reprocessing chemical or additional mechanical wear to the subject device requiring additional testing.

Clinical Testing
No clinical studies were performed as the automated cleaning process and reduced rinsing steps of the existing manual cleaning process do not introduce harsher reprocessing chemical or additional mechanical wear to the subject device requiring additional testing.

8. Conclusion

Based upon the intended use, design, operating principles, comparison to the predicate devices, and conducted testing, it is concluded that the subject devices reprocessed via an automated cleaning process and reduced rinsing steps of the existing manual cleaning process are substantially equivalent to the predicate devices reprocessed via the current manual cleaning process. Testing also supports that the subject devices reprocessed via an automated cleaning process and reduced rinsing steps of the existing manual cleaning process do not raise any new risks or any new questions in safety or effectiveness for the subject devices.