April 3, 2024

Intuitive Surgical, Inc.
Jennifer Siu
Regulatory Project Manager
1266 Kifer Road
Sunnyvale, California 94086

Re: K240135
Trade/Device Name: Ion™ Endoluminal System (Ion™ Fully Articulating Catheter) (IF1000)
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: January 17, 2024
Received: January 18, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Joyce C. Lin -S

for Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240135

Device Name

Ion™ Endoluminal System (Ion™ Fully Articulating Catheter) (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
Regulatory Project Manager
Tel: (408) 523-5372
Email: jennifer.siu@intusurg.com

Date of Submission: January 17, 2024

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 (K212048), cleared on August 26, 2021.

4. Device Description

The Ion™ Endoluminal System (hereinafter referred to as the Ion System) 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 Ion System 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 Ion System 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 Ion System Instrument, specifically the Ion™ Fully Articulating Catheter (Catheter), subject to the scope of change under this submission, remains substantially equivalent to the Ion System Instrument cleared under K212048. There were no changes in design or reprocessing instructions for the subject device as a result of the increase in use life from 5 use lives to 8 use lives for the Catheter.

Intuitive is increasing the use life of the Catheter to 8 use lives. 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 use life increase. **Table 1** provides a comparison between the subject device and predicate device.

Table 1. Comparison of Predicate and Subject Devices

	Predicate Device: Ion System Catheter (K212048)	**Subject Device: Ion System Catheter (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
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	SAME as predicate

	Predicate Device: **Ion System** **Catheter** **(K212048)**	**Subject Device:** **Ion System** **Catheter** **(This Submission)**
	procedures. The Ion™ Endoluminal System enables fiducial marker placement. It does not make a diagnosis and is not for pediatric use	
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 Tip Articulation Range	180° in all four directions (pitch and yaw)	SAME as predicate
Catheter Tool Channel Diameter	2 mm	SAME as predicate
Catheter Patient Contact Materials	Stainless steel Silicone Pellethane plastic PTFE plastic Cyanoacrylate Gold-Tin solder	Stainless steel Silicone Pellethane plastic PTFE plastic Cyanoacrylate
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 or Automated cleaning and automated microbicidal process	SAME as predicate
Use Life	5	8

Cleaning validation results demonstrate that the subject device with 8 use lives is substantially equivalent to the predicate device with 5 use lives. Furthermore, the testing did not raise any new risks or new or different 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 cleaning validation, toxicological risk assessment, and bench testing.

Cleaning Validation

The Catheter and its current reprocessing instructions were validated to support cleaning efficacy for 8 use lives. Testing was performed in accordance with AAMI TIR12:2020 *Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers* and AAMI ST98:2022 *Cleaning validation of health care products - Requirements for development and validation of a cleaning process for medical devices*. Testing passed the predetermined acceptance criteria.

Biocompatibility

In order to confirm that there was no new or increase biological risk for the subject Catheter with 8 use lives, for the entire use life of the device in accordance with the latest ISO 10993-1:2018 *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*, cytotoxicity testing was performed in accordance with ISO 10993-5:2009 *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity*. Testing passed the predetermined acceptance criteria and did not signal new or different biological risks.

Bench Testing

A series of bench testing was performed to verify and validate that the Catheter continues to meet the existing functional requirements for 8 use lives. Reliability (life) testing and design verification testing for instrument to system software compatibility were performed. All testing passed the predetermined acceptance criteria.

Animal Testing

No animal studies were performed as the subject device with 8 use lives does not introduce new or different risks that requiring additional testing.

Clinical Testing

No clinical studies were performed as the subject device with 8 use lives does not introduce new or different risks that 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 device with 8 use lives is substantially equivalent to the predicate device with 5 use lives. Testing also supports that the subject device with 8 use lives does not raise any new risks or new or different questions in safety or effectiveness.