September 24, 2024

Intuitive Surgical, Inc.
Farzin Bolourchian
Regulatory Affair Technical Lead
1266 Kifer Road
Sunnyvale, California 94086

Re: K242070
Trade/Device Name: Ion Endoluminal System (IF 1000)
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: July 15, 2024
Received: July 16, 2024

Dear Farzin Bolourchian:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

Enclosure

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)*

K242070

Device Name

Ion Endoluminal System (IF 1000)

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 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.

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of Safe Medical Device Act (SMDA) 1990 and 21 CFR 807.92.

1. SUBMITTER

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

Contact: Farzin Bolourchian
Regulatory Affairs, Technical Lead
Phone Number: 408-425-5233
Email: farzin.bolourchian@intusurg.com

Date Prepared: July 15, 2024

2. SUBJECT DEVICE INFORMATION

Manufacturer Name:	Intuitive Surgical, Inc.
Trade Name:	Ion Endoluminal System, Model IF1000
Common Name:	Bronchoscope (flexible or rigid) and accessories
Classification:	Class II 21 CFR 874.4680
Product Codes:	EOQ
Review Panel:	Ear, Nose, and Throat

3. PREDICATE DEVICE INFORMATION

Manufacturer Name:	Intuitive Surgical, Inc.
510(k) Number:	**K232984**, last cleared on December 18, 2023
Trade Name:	Ion Endoluminal System, Model IF1000
Common Name:	Bronchoscope (flexible or rigid) and accessories
Classification:	Class II 21 CFR 874.4680
Product Codes:	EOQ
Review Panel:	Ear, Nose, and Throat

No reference devices were used in this submission.

4. 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 follower portion of the servomechanism, and two monitors. The System Cart allows the user to navigate the Catheter Instrument with the Controller, which represents the leader in the leader-follower 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 IF1000 System and PlanPoint Software are modified to enable Remote Software Updates from the Intuitive server via secure network communication.

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 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 OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device (Ion Endoluminal System, Model IF1000) has been developed by modifying the predicate device, the Ion Endoluminal System, Model IF1000 **(K232984**).

The subject device and the predicate device, Ion Endoluminal System, have the same intended use, indications for use, operating principles, and similar technological characteristics. A summary of the technological characteristics of the subject device compared to the predicate device is provided below:

Description	**Predicate Device (K232984)** Ion Endoluminal System, Model IF1000	**Subject Device** Ion Endoluminal System, Model IF1000
Regulation Number	21 CFR §874.4680	Identical to the predicate device
Classification	Class II	identical to the predicate device
Product Code	EOQ	Identical to the predicate device
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 PlanPoint Software uses patient CT scans to create a 3D plan of the lung and navigation pathways for use with the Ion Endoluminal System.	Identical to the predicate device
Intended Use	To provide access to and visualization of patient airways.	Identical to the predicate device
Prescription use	Rx only	Identical to the predicate device
Use Environment	Hospital	Identical to the predicate device

Description	Predicate Device (K232984) Ion Endoluminal System, Model IF1000	Subject Device Ion Endoluminal System, Model IF1000
Principles of operations	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 Leader/follower servomechanism incorporates servo motor control and system-level coordinated joint control.	Identical to the predicate device
Major Subsystems		
System Cart and Controller	The System Cart allows users to navigate the Catheter with user inputs from the Controller.	Identical to the predicate device
System Software	Enables control of the Catheter instrument, System Cart, and Controller to support the System functions. It also performs a variety of additional functions, such as monitoring sensors throughout the system, generating the user interface display outputs, and providing interfaces for manufacturing.	Added support to enable Remote Software Update from the Intuitive server via secure network communication.
Planning Laptop with PlanPoint Software	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.	Added support to enable Remote Software Update from the Intuitive server via secure network communication.

The added support for the Remote Software Update feature mentioned on the subject and predicate device comparison table above is further discussed in the following section. The IF1000 System and PlanPoint Software have been modified to perform remote software update over a network connection without requiring an Intuitive field service engineer to visit the site. The software update can only be initiated by the user when the device is not in use in a clinical procedure. This capability is not required for the device's intended use and does not impact the device's safety and clinical performance. Additionally, this feature does not raise different questions of safety and effectiveness, as confirmed through testing

of the subject device. Thus, the subject and the predicate device are substantially equivalent.

7. PERFORMANCE DATA

Performance testing data demonstrates that the subject device is substantially equivalent to the predicate device and that the design output meets the design input requirements. The performance testing for the Ion Endoluminal System included software verification and validation, including cybersecurity and design validation, using simulated animal models.

Software Verification and Validation

The System and PlanPoint software underwent verification and validation testing. The software testing included the unit, subsystem integration, and system level testing. The software testing results demonstrate that the System and PlanPoint software meets design specifications and user needs. Each software was also subjected to regression testing. The regression testing verified that the subject device modifications did not impact the unmodified elements of the System and PlanPoint software. Software documentation has been provided per FDA Guidance "Content of Premarket Submissions for Device Software Functions," issued June 14, 2023.

Cybersecurity Testing

The cybersecurity verification and validation testing were conducted, and cybersecurity was evaluated per the FDA's final guidance, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions", issued on September 27, 2023. The cybersecurity verification and validation test results demonstrate the adequacy of the implemented cybersecurity controls.

Animal Testing

For system design validation, in-vivo animal testing was performed under simulated use conditions to assess the system performance. The test results demonstrate that the System performs effectively according to its intended use and does not raise different questions of safety or effectiveness.

Usability Testing

Changes to the subject device do not affect previously identified critical tasks, and no new critical tasks were identified. Therefore, data collected during the previous summative usability study for the predicate device, the Ion Endoluminal System (K182188), remains valid, and no additional testing was required.

8. CONCLUSION

The subject device and the predicate device, Ion Endoluminal System (**K232984**), have the same intended use, indications for use, operating principles, and similar technological characteristics. The subject device modifications have been evaluated and do not raise different questions of safety or effectiveness. The performance testing data confirmed that the device performs as intended to its specifications and meets its intended use.

Based on the intended use, indications for use, operating principles, technological characteristics, and performance testing, the subject device, Ion Endoluminal System, is substantially equivalent (SE) to the predicate device.