June 16, 2022

Intuitive Surgical, Inc.
Jyoti Singh
Sr. Regulatory Affairs Specialist
1266 Kifer Road
Sunnyvale, California 94086

Re: K220299
Trade/Device Name: Ion Endoluminal System (IF1000)
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: May 16, 2022
Received: May 17, 2022

Dear Jyoti Singh:

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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220299

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

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: Jyoti Singh
Senior Regulatory Specialist
Phone Number: 408-523-5315
Email: jyoti.singh@intusurg.com

Date Prepared: February18, 2022

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 Bronchoscope (flexible or rigid) and accessories
Product Codes:	EOQ
Review Panel:	Ear, Nose, and Throat

3. PREDICATE DEVICE INFORMATION

Manufacturer Name:	Intuitive Surgical, Inc.
510(k) Number:	**K202370**, last cleared on November 16, 2020
Trade Name:	Ion™ Endoluminal System, Model IF1000
Common Name:	Bronchoscope (flexible or rigid) and accessories
Classification:	Class II 21 CFR 874.4680 Bronchoscope (flexible or rigid) and accessories
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 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 IF1000 System software is modified to optionally receive an intra-procedural cone beam CT image to enhance the virtual target location based on user input.

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 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 (K202370**).

The subject device and the predicate device, Ion™ Endoluminal System (**K202370**) are based on 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 (K202370)** 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 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	Identical to the as predicate device

Description	Predicate Device (K202370) Ion™ Endoluminal System, Model IF1000	Subject Device Ion™ Endoluminal System, Model IF1000
	of the lung and navigation pathways for use with the Ion™ Endoluminal System.	
Intended Use	To provide access to and visualization of patient airways.	Identical to the as predicate device
Prescription use	Rx only	Identical to the predicate device
Use Environment	Hospital	Identical to the predicate device
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 Master/slave servomechanism incorporates servo motor control and system-level coordinated joint control.	Identical to the predicate device
Major subsystems	• System Cart and Controller with incorporated System Software • Planning Laptop with PlanPoint™ Software	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 variety of additional functions, such as monitoring sensors throughout the system, generating the user interface display outputs, and providing interfaces for manufacturing.	added interoperability with the integrated CBCT system to support the integrated CBCT feature

7. PERFORMANCE DATA

Performance testing data demonstrates the subject device is substantially equivalent to the predicate device (**K202370**), and the design output meets the design input requirements. The performance testing included software verification and validation, including cybersecurity, and design validation, using simulated animal model.

Software Verification and Validation

Software documentation has been provided according to FDA's Guidance for Industry and FDA "The Content of Premarket Submissions for Software Contained in Medical Devices" (May 11, 2005.). The System software underwent verification and validation testing. The software testing included unit, subsystem, system level and interoperability testing. The interoperability approach is in alignment with FDA guidance, Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices (September 6, 2017). The software testing results demonstrate the System meets design specifications and user needs. The System software was also subjected to regression testing using same test methods and acceptance criteria presented in the predicate device premarket notification **K202370**. The regression testing verified that the subject device modifications did not impact the unmodified elements of the IF1000 System software.

Cybersecurity Testing

The cybersecurity verification and validation testing was conducted, and cybersecurity was evaluated per FDA's Draft Guidance "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" (October 18, 2018). Specifically, addressing the following areas: Identify and Protect, Detect, Response and Recover. 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 and accuracy. The test results demonstrate that the System performs effectively according to its intended use and does not raise different questions of safety or effectiveness.

8. CONCLUSION

The subject device and the predicate device, **Ion™ Endoluminal System** (**K202370**) 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 (**K202370**).