



November 16, 2020

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

Re: K202370

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 18, 2020
Received: August 19, 2020

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 Malvina B. Eydelman, M.D.
Director
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K202370

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
Fax Number: 408-523-8907
Email: jyoti.singh@intusurg.com

Date Prepared: Aug 18, 2020

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: K182188, last cleared on February 14, 2019
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

4. REFERENCE DEVICE INFORMATION

Manufacturer Name: Intuitive Surgical, Inc.

510(k) Number: K182643, last cleared on February 22, 2019

Trade Name: IRIS 1.0 System

Common Name: System, surgical, computer-controlled instrument

Classification: Class II

21 CFR §892.2050, Picture archiving and communications system

Product Codes: LLZ

Review Panel: Radiology

5. 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 Ion™ Endoluminal System enables automatic device logs retrieval via the network and connects to a hospital networked Picture Archiving and Communication System (PACS).

6. 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.

7. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

7.1 Comparison of Subject with the Predicate Device

The subject of this submission, Ion™ Endoluminal System, Model IF1000 has been developed by modifying **Ion Endoluminal System, Model IF1000 (K182188)**.

The subject device and the predicate device, Ion™ Endoluminal System (K182188) are based on the same intended use, indications for use, operating principles and similar technological characteristics. A brief summary of the technological characteristics of the subject device compared to the predicate device is provided below:

Description	Predicate Device <i>Ion™ Endoluminal System, Model IF1000 (K182188)</i>	Subject Device <i>Ion™ Endoluminal System, Model IF1000 (Not assigned)</i>
Regulation Number	21 CFR §874.4680	SAME as Predicate device
Classification	Class II	SAME as Predicate device
Product Code	EOQ	SAME as Predicate device

Description	Predicate Device <i>Ion™ Endoluminal System, Model IF1000 (K182188)</i>	Subject Device <i>Ion™ Endoluminal System, Model IF1000 (Not assigned)</i>
Indications for use	<p>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.</p> <p>The Flexision™ Biopsy Needle is used with the Ion™ Endoluminal System to biopsy tissue from a target area in the lung.</p> <p>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.</p>	SAME as Predicate device
Intended Use	To provide access to and visualization of patient airways.	SAME as Predicate device
Prescription use	Rx only	SAME as Predicate device
Use Environment	Hospital	SAME as Predicate device

Description	Predicate Device <i>Ion™ Endoluminal System, Model IF1000 (K182188)</i>	Subject Device <i>Ion™ Endoluminal System, Model IF1000 (Not assigned)</i>
Principles of operations	<p>Visualization of endoluminal spaces via light delivery and video</p> <p>Naviga tion through endoluminal spaces via tip deflection capabilities</p> <p>Provides a working channel through which other instruments can be delivered to target sites within the airways</p> <p>Master/slave servomechanism incorporates servo motor control and system-level coordinated joint control.</p>	SAME as Predicate device
Major subsystems	<ul style="list-style-type: none"> • System Cart and Controller with incorporated System Software • Planning Laptop with PlanPoint™ Software 	SAME as Predicate device
Log retrieval	Manual retrieval via a USB	SAME as Predicate device with added support for a utomatic retrieval via the network.
Procedure planning	PlanPoint™ Software uses DICOM CT scan for preoperative planning. CT scan sources include CD, DVD and USB	SAME as predica te device with added support for using hospital networked PACS as a CT scan source.

7.2 Comparison of Subject with the Reference Device

The reference device, IRIS 1.0 System (K182643) supports the DICOM CT image access via the hospital networked PACS. Same as the subject device (Ion™ Endoluminal System), the IRIS 1.0 system has the capability to query and retrieve DICOM CT from a hospital networked PACS. The DICOM CT query and retrieve feature of the reference device is analogous to the similar feature in the subject device. A brief summary of the technological characteristics of the subject device compared to the reference device is provided below:

Description	Reference Only Device <i>IRIS 1.0 System (K182643)</i>	Subject Device <i>Ion™ Endoluminal System, Model IF1000</i>
Manufacturer	Intuitive Surgical, Inc.	SAME as reference device
Common Name	System, surgical, computer-controlled instrument	Bronchoscope (flexible or rigid) and accessories
Trade Name	IRIS 1.0 System	Ion™ Endoluminal System
Classification	Class II	SAME as reference device
Regulation description and Number	Picture archiving and communications system (21 CFR §892.2050)	Bronchoscope (flexible or rigid) and accessories (21 CFR §874.4680)
Product Code	LLZ	EOQ
Review panel	Radiology	Ear, Nose, and Throat
Prescription use	Rx only	SAME as reference device
Use Environment	Hospital and office setting	SAME as reference device, but does not include office setting
PACS DICOM CT scan Access	IRIS 1.0 software (Cloud based mobile software) uses DICOM CT scan images for preoperative planning. DICOM CT images are accessed from the hospital networked PACS via query/retrieve processes.	PlanPoint™ Software (installed on Planning Laptop) uses DICOM CT scan images for preoperative planning. DICOM CT images are accessed from the hospital networked PACS via query/retrieve and listen processes. Query/retrieve process of PlanPoint™ Software is SAME as reference device.

8. PERFORMANCE DATA

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

Biocompatibility Testing

The scope of this submission does not include changes to patient-contacting components of the Ion™ Endoluminal System, IF1000 therefore, no biocompatibility testing was needed.

EMC and Electrical Safety Testing

The predicate device (K182188) was tested for EMC under IEC 60601-1-2:2007, whereas the subject device (Ion Endoluminal System) was tested for compliance with the new 4th edition version of the standard, IEC 60601-1-2: 2014.

The 4th edition EMC testing of the subject device also verified hardware modifications made to the subject device. These modifications consist of the addition of a PCA board called the Wally Network Node (WNN) and a Network Security Device to support networking interfaces.

The electrical safety testing performed for compliance with IEC 60601-1 and IEC 60601-2-18 on predicate device (K182188) remains valid for the subject device because the scope of changes for this submission do not impact the electrical safety of the Ion Endoluminal System.

Software Verification and Validation

Software for the Ion™ Endoluminal System underwent verification and validation testing, results demonstrate the System meets design specifications and user needs. Software documentation has been provided according to FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued May 11, 2005.

Bench testing

The System Cart and Planning Laptop were subjected to bench testing and results confirm the design outputs for the System Cart and the Planning Laptop meet the design input requirements. No hardware changes were made to the Controller. Therefore, no performance bench testing was required for the Controller.

Cybersecurity testing

The Ion™ Endoluminal System was subjected to Cybersecurity verification and validation testing. 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, animal testing was performed under simulated use conditions to assess the system performance. Test results demonstrated the Ion™ Endoluminal System performs according to its intended use.

Usability Testing

Changes made 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.

Clinical Testing

No clinical testing was required to validate the changes made to the Ion™ Endoluminal System.

9. CONCLUSION

The subject device and the predicate device, Ion™ Endoluminal System (K182188), have the same intended use, indications for use, operating principles and similar technological characteristics. Same as the subject device (Ion™ Endoluminal System) the reference device (Iris System 1.0, K182643) has the capability to query and retrieve DICOM CT from a hospital networked PACS.

The device modifications made to enable the network communication and direct patient CT scan images download via PACS server on the hospital network 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 Ion™ Endoluminal System is substantially equivalent (SE) to the predicate device.
