



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Covidien LLC
% Ms. Jenny Jiang
Manager, Regulatory Affairs
161 Cheshire Lane, Suite 100
PLYMOUTH MN 55441

November 5, 2015

Re: K151376
Trade/Device Name: superDimension™ Navigation System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: October 2, 2015
Received: October 5, 2015

Dear Ms. Jiang:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017

See PRA Statement below.

510(K) Number (if known)

K151376

Device Name

superDimension™ Navigation System

Indications for Use (Describe)

Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool. Not for pediatric use.

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

Covidien llc

Traditional 510(k): superDimension™ Navigation System

The contents of the 510(k) Summary have been provided in conformance with 21 CFR 807.92.

1. Submitter

510(k) Submitter:

Covidien llc
161 Cheshire Lane, Suite 100
Plymouth, MN 55441 U.S.A.

Contact Person:

Jenny Jiang
Regulatory Affairs Manager
Phone: 763-647-5531
Fax: 763-210-4098
Email: jenny.jiang@covidien.com

Date Prepared: October/2/2015

2. Subject Device

Trade Name : superDimension™ Navigation System
Common Name: Bronchoscope
Classification Name: Computed tomography x-ray system
21 CFR 829.1750
Product code: JAK
Manufacturer: Covidien llc

3. Predicate Device

Device Name : superDimension iLogic™ inReach System
Common Name: Bronchoscope
510(k): K102604
Classification Name: Computed tomography x-ray system
21 CFR 829.1750
Product code: JAK
Manufacturer: Covidien llc

4. Device Description

The superDimension™ navigation system is a device that guides a bronchoscope and endoscopic tools to a target in or adjacent to the bronchial tree on a path identified by CT scan. The superDimension™ navigation system also allows visualization of the target and the interior of the bronchial tree; placement of catheters in the bronchial tree; and placement of radiosurgical and dye markers into soft lung tissue to guide radiosurgery and thoracic surgery.

Covidien llc is introducing the superDimension™ navigation system software release version 7.1, which is a software modification to the predicate device superDimension iLogic™ inReach System cleared under 510(k) K102604.

5. Indications for Use

Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool. Not for pediatric use.

6. Summary of Characteristics Compared to Predicate Device

Both the subject device and predicate devices have the same indications for use, principle of operation, technological and performance characteristics. The proposed superDimension™ navigation system version 7.1 implements several software features including Pathway Planning on 3D Map, Fiducial Placement, and some minor software enhancements. No changes are being made to the disposable products, system hardware components, or fundamental scientific technology of the superDimension™ navigation system. The Instructions for Use is being updated to address the changes to the software. There has been no modification to intended use or indications for use.

The primary differences between the subject and predicate devices are additional software features and minor software enhancements. The software changes in the subject device provide additional software functionalities to end users. However, these software changes don't alter the intended use of the device since these changes have no impact on the fundamental scientific technology, software core algorithms, principle of operation, or performance characteristics of the superDimension™ navigation system.

Design verification and validation test results demonstrate that the changes don't affect the safety and effectiveness of the device as the subject device conforms to the requirements and specifications of the device.

7. Performance Data

The changes to the software and Instructions for Use were subjected to the Covidien design control process. Risk Management was performed to analyze the potential hazards associated with the changes. Appropriate design verification and validations were performed to assure the superDimension™ navigation system version 7.1 continues to meet its intended use.

Design verification performed on the superDimension navigation system V7.1 Planning and Procedure application and confirmed that the superDimension navigation system met its product specification and system requirements. A full regression testing was executed to verify the modifications and ensure that the superDimension navigation system meets its product specification and requirements.

Design validation was performed under simulated use conditions at the Covidien llc facility in Plymouth, MN and the facility in Herzliya, Israel by representative users from each targeted user group that include qualified bronchoscopists, clinician, and service technicians. Each user group performed typical use scenario defined in the design validation protocol. 100 % of users across the three categories (bronchoscopists, clinicians, and service personnel,) successfully completed validation tasks. In conclusion, the design validation study ensured that the Version 7.1 superDimension™ Navigation System with planning and procedure software version 7.1, conform to defined user needs and intended uses.

The superDimension™ navigation system is in compliance with the following International and FDA-recognized consensus standard:

- ISO 14971: 2007 Medical Devices - Application of Risk Management to Medical Devices

8. Clinical Data

Clinical tests were not required to validate the changes to the superDimension™ navigation system.

9. Conclusion

The superDimension™ navigation system V7.1 has the same indications for use, principle of operation, technological and performance characteristics as the predicate device K102604. Design verification and validation test results provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its indications for use and intended use. Covidien llc considers the superDimension™ navigation system V7.1 to be substantially equivalent to legally marketed predicate device superDimension iLogic™ inReach System (K102604).