Covidien LLC
% Ms. Kristen Swanson
Regulatory Affairs Consultant
Kompass Regulatory Consulting, LLC
1583 Northrop Street
FALCON HEIGHTS MN 55108

February 8, 2018

Re: K173244
Trade/Device Name: superDimension™ Navigation System V7.2
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: January 11, 2018
Received: January 16, 2018

Dear Ms. Swanson:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173244

Device Name
superDimension™ Navigation System V7.2

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) K173244
superDimension™ Navigation System v7.2

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:
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Principal Regulatory Affairs Specialist
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Date Prepared: 10/05/2017

2. Subject Device

Trade Name :	superDimension™ Navigation System V7.2
Common Name:	Electromagnetic Navigation Bronchoscopy System
Classification Name:	Computed tomography x-ray system 21 CFR 829.1750
Product code:	JAK
Manufacturer:	Covidien llc

3. Predicate Device

Device Name :	superDimension™ Navigation System
Common Name:	Electromagnetic Navigation Bronchoscopy System
510(k):	K151376
Classification Name:	Computed tomography x-ray system 21 CFR 829.1750
Product code:	JAK
Manufacturer:	Covidien llc

4. Device Description

The superDimension™ navigation system version 7.2 (V7.2) is a device that guides endoscopic tools to a target in or adjacent to the bronchial tree on a path identified by a previous CT scan. The superDimension™ navigation system V7.2 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 V7.2, which is a software modification to the predicate device superDimension navigation system cleared under 510(k) K151376. The V7.2 software includes an optional local registration feature intended to compensate for CT-to-body divergence though incorporation of additional fluoroscopic imaging data taken during the electromagnetic navigation procedure. Local registration is an optional feature and can be used at the physician's discretion.

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

The subject and predicate devices have identical indications for use. Both the subject and predicate devices include the same system hardware, Planning software, disposable sterile devices, and disposable non-sterile components. The proposed superDimension™ navigation system version 7.2 includes a Procedure application software modification and one additional standalone hardware component, called a fiducial marker board. The software change implements an optional local registration feature. The local registration feature uses a fluoroscopic video taken during the procedure and a fiducial marker board to allow 3D reconstruction of a small region of interest in the lung to compensate for possible CT-to-body divergence.

The only difference between the subject and predicate devices is one additional software feature, an additional fiducial board, and an updated user manual. The changes in the subject device provide an additional software function to end users. However, the changes do not 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 do not 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, fiducial marker board, 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 V7.2 continues to meet its intended use.

Design testing performed on the superDimension navigation system V7.2 included the following:

- Software verification testing including target visualization and marking accuracy, local registration accuracy, software application testing and regression testing
- Usability validation testing with qualified bronchoscopists and clinicians to confirm functionality and user interface
- Fiducial marker board design verification and shipping validation.

The combined verification and validation testing confirmed that the superDimension navigation system V7.2 met its product specification and system requirements. Regression testing was executed to verify the modifications did not impact unmodified software elements.

Design validation was successfully performed under simulated use conditions by representative users from targeted user groups including qualified bronchoscopists and clinicians. Each user group performed typical use scenarios defined in the design validation protocol. In conclusion, the design validation study ensured that the superDimension™ navigation system V7.2 conformed 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
- IEC 62366-1: 2015 Medical devices - Part 1: application of usability engineering to medical devices
- ISO 15223-1: 2016 Medical devices - symbols to be used with medical device labels, labelling, and information to be supplied - part 1: general requirements.
- ASTM D4169: 2016 Standard Practice for Performance Testing of Shipping Containers and Systems
- ANSI/AAMI/IEC 62304: 2006 Medical device software - software life cycle processes

8. Clinical Data

Clinical tests were not required to validate the changes to the superDimension™ navigation system V7.2.

9. Conclusion

The superDimension™ navigation system V7.2 has the same indications for use, principle of operation, fundamental scientific technology, and performance characteristics as the predicate device K151376. 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. A thorough risk assessment has shown that the addition of the local registration feature does not significantly change the device risks. Covidien llc considers the superDimension™ navigation system V7.2 to be substantially equivalent to the legally marketed predicate device superDimension navigation system cleared under 510(k) K151376.