K110093

FEB 1 1 2011

510(k) SUMMARY
superDimension® Marker Delivery Kit

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

Submitter Information	
Name	superDimension, Ltd.
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Establishment Registration Number	3004659744
Name of contact person	Jonathan Kovach Vice President, Quality and Regulatory Affairs 763-210-4000
Date prepared	01/10/2011
Name of device	
Trade or proprietary name	superDimension i·Logic inReach System superDimension inReach System superDimension/Bronchus
Common or usual name	Bronchoscope
Classification name	Computed tomography x-ray system
Classification panel	Radiology
Regulation	21 CFR Part 892.1750
Product Code(s)	JAK
Legally marketed device(s) to which equivalence is claimed	superDimension i·Logic inReach System, K071473/K092365/K102604
Reason for 510(k) submission	Introduction of accessory Marker Delivery Kit for the placement of markers into soft lung tissue using the superDimension i·Logic inReach System.
Device description	The superDimension i·Logic inReach 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 i·Logic inReach 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.
Intended use of the device	Enable the diagnosis and treatment of lung cancer.

dications 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.

Summary of the technological characteristics of the device compared to the predicate device

Characteristic	Comparison to New Device
Indications for Use	Same
Anatomical Sites	Same
Basic Principle	Same
Localization Methodology	Same
Visualization Principle and Method of Visualization of Path and Organs	Same
Display Methods	Same
Interventional Instrument	Same. Accessory Marker Delivery Kit is being added.
Method of tracking location	Same
Computer function and type	Same
Energy Released into Body (Negligible)	Same
Compatibility with other devices	Same. Accessory Marker Delivery Kit is being added.
.ocompatibility	Same. Accessory Marker Delivery Kit is being added.
Medical electrical equipment safety compliance	Same
Registration Modes and Navigation Guidance	Same
Software	Same
Sterile Accessories	Same. Accessory Marker Delivery Kit is being added.
Marker Placement	Same. Accessory Marker Delivery Kit is being added.

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Performance Test Summary-New Device

The superDimension Marker Delivery Kit and Instructions for Use were subjected to the superDimension 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 i·Logic inReach System continues to be safe and effective for its intended use.

Comparative Performance Information Summary

Not Required to validate the changes to the superDimension System.

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION

Clinical tests were not required to validate the changes to the superDimension System.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

The superDimension i·Logic inReach System with the accessory Marker Delivery Kit is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

FEB 11 2011

superDimension, Ltd.
% Mr Jonathan Kovach
Vice President, Quality and Regulatory Affairs
superDimension, Inc.
161 Cheshire Lane, Suite 100
MINNEAPOLIS MN 55441

Re: K110093
Trade/Device Name: superDimension® Marker Delivery Kit
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: January 10, 2011
Received: January 12, 2011

Dear Mr. Kovach:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110093

Device Name: superDimension® Marker Delivery Kit

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.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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