K082380

SEP 16 2008

510(k) Summary

superDimension, Ltd.
Special 510(k)
Proposed Minor Modifications to inReach™ Planning Laptop

Date Prepared:

08/18/2008

510(k) Applicant:

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510(k) Application Correspondent:

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Name of Device :

Trade Name :	- superDimension®/ inReach™ Planning Laptop - inReach™ Planning Laptop
Common Name:	inReach™ Planning Laptop - Bronchoscopy Planning/CT-Viewing
Classification Name:	Picture Archiving and Communications System 21 CFR 892.2050 Product code LLZ

Equivalent Legally-Marketed Device:
inReach System, K081379

Description:

superDimension is proposing that the inReach™ Planning Laptop, with its current software be approved to be used either as a stand-alone for performing bronchoscopy planning, as currently approved (K081379, June 11, 2008) or for CT-Viewing, or with the other system components in places outside of the endoscopy room.

There are no modifications proposed to the software, hardware, firmware, product design or specifications, or manufacturing processes as currently approved.

Intended 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 Characteristics Compared to Predicate Device:

Minor modifications are being proposed to the Instruction for Use (inReach User Manual) to reflect the proposal that the Planning Laptop be used as a stand-alone for bronchoscopy planning or CT-Viewing, or with the other system components.

No changes are being made to the hardware or intended use, or technological characteristics of the current marketed device.

Performance Data:

The planned modifications were subjected to the superDimension design control process. There are no modifications proposed to the software, hardware, firmware, product design or specifications, or manufacturing processes as currently approved (K081379, June 11, 2008). The inReach System and software design input/output requirements are not changing and will continue to meet the user needs and intended uses, performing to design specifications. Therefore software and design validations/verifications are not required to be performed.

There are no new, increased, altered, or eliminated risks associated with this minor modification. A risk analysis is not required to be performed. The risk analysis documents presented in K081379 have not changed, and still apply to the Planing Laptop.

Appropriate labeling changes are identified in the User Manual and summarized in the User Manual Change Revision Table.

Clinical Data:

Clinical tests were not required to validate the changes to the inReach System to incude the Planning Laptop.

Conclusion:

The inReach System is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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superDimension, Ltd.
% Ms. Margaret DePuydt
Regulatory Affairs Manager
superDimension, Inc.
161 Cheshire Lane, Suite 100
MINNEAPLOIS MN 55441

Re: K082386
Trade/Device Name: inReach Planning Laptop
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 15, 2008
Received: August 19, 2008

Dear Ms. DePuydt:

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 either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082386

Device Name: inReach Planning Laptop

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082386