FEB 2 4 2012

510(K) SUMMARY

510(K) Number K 120301

Applicant's Name:

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MediGuide Navigation Systems
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And/Or

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Date Prepared:

January, 2012

Trade Name:

MediGuide Technology

Classification Name:

Programmable diagnostic computer

Product Code:
DQK

Device Class:
II

Regulation Number:
870.1425

Panel:
Cardiovascular

Predicate Devices:
Guided Medical Positioning System II (gMPS™ II) [MediGuide Ltd.] cleared under K102905.

Intended Use / Indications for Use:
The MediGuide Technology System is intended for the evaluation of vascular and cardiac anatomy. It is intended to enable real time tip positioning and navigation of a MediGuide enabled (equipped with a MediGuide sensor) diagnostic or therapeutic invasive device used in vascular or cardiac interventions in the Cath Lab environment, on both live fluoroscopy or recorded background. The System is indicated for use as an adjunct to fluoroscopy.

Device Description:
The MediGuide Technology System, used in conjunction with an X-ray System, employs magnetic positioning technology to track a MediGuide enabled diagnostic or therapeutic invasive device for the 3D position relative to any X-Ray image, in real-time or previously recorded cine-loop.

The MediGuide Technology System includes two optional software packages. The Coronary package includes the Coronary application, and it supports coronary procedures. The Cardiac package includes the Cardiac Navigation application and the Cardiac Navigation with Angio Survey™ application, both support cardiac procedures.

The most fundamental capability of the MediGuide Technology is the positioning and navigation of MediGuide enabled devices. This feature enables projection of the real time position of a MediGuide sensor (and thus of the MediGuide enabled device) on real time 2D X-Ray images (live mode) or in a recorded mode (the MediGuide enabled device tip real time position is superimposed on a previously recorded cine loop or still image). The MediGuide Technology enables simultaneous tracking of up to three MediGuide enabled devices.

In addition, the MediGuide Technology provides the following features:

- Landmarking (for both coronary and cardiac procedures)
- 3D reconstruction model (for both coronary and cardiac procedures)
- Trace rendering (Smart trace for coronary procedures, and shaft rendering for cardiac procedures)
- 2D fusion (for cardiac procedures)
- 3D measurements (for coronary procedures)
- Quantitative Coronary Angiography (for coronary procedures)

Substantial Equivalence:

The intended use and indications for use of the MediGuide Technology are identical to the intended use and indications for use of its predicate device, the gMPS™ II system. In addition, the same technological characteristics and principles of operation apply for both the MediGuide Technology system and its predicate device.

Performance testing was conducted in order to demonstrate the performance and accuracy of the MediGuide Technology and to verify that all the modifications introduced in the device as compared to its predicate device did not raise any new safety and effectiveness issues.

Test results indicated that the MediGuide Technology is as safe and effective as its predicate device for its intended use and is substantially equivalent to its predicate device without raising any new safety and/or effectiveness issues.

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 24 2012

St. Jude Medical, Inc.
c/o Mr. Jonathan S. Kahan, Esq.
Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004

Re: K120301
Trade/Device Name: MediGuide Technology
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable diagnostic computer
Regulatory Class: Class II (two)
Product Codes: DQK
Dated: January 31, 2012
Received: January 31, 2012

Dear Mr. Kahan:

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120301

Device Name: MediGuide Technology

Indications For Use:

The MediGuide Technology system is intended for the evaluation of vascular and cardiac anatomy. It is intended to enable real time tip positioning and navigation of a MediGuide enabled (equipped with a MediGuide sensor) diagnostic or therapeutic invasive device used in vascular or cardiac interventions in the Cath Lab environment, on both live fluoroscopy or recorded background. The System is indicated for use as an adjunct to fluoroscopy.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120301