Planmed

K121963

510K) SUMMARY

DATE
October 12, 2012

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PRODUCT, CLASSIFICATION NAME
Trade name: Planmed Nuance DigiGuide
Common name: Stereotactic biopsy for Full Field Digital Mammography (FFDM) System
Classification: MUE, Class II
Regulation number: 21 CFR 892.1715

MANUFACTURER
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Roselle, IL 60172
Phone: (630) 529 2300
Fax: (630) 529 1929
Contact person : Bob Pienkowski

INTENDED USE
Planmed Nuance DigiGuide is an optional system for stereotactic biopsy. It consists of a needle guidance unit attached to Planmed Nuance or Planmed Nuance Excel digital mammographic X-ray units.

The system is used for needle sampling of women's breast tissues for examination. The use of Planmed Nuance DigiGuide is allowed only under supervision of a health care professional.

PRODUCT DESCRIPTION
Planmed Nuance DigiGuide is a digital biopsy imaging system. This system is compatible with Planmed Nuance and Planmed Nuance Excel FFDM X-ray units.

The Planmed Nuance DigiGuide system consists of the FFDM X-ray unit (Planmed Nuance or Planmed Nuance Excel) that is equipped with the needle guidance unit and the acquisition workstation (AWS), including a personal computer with the Nuance Manager 3 software, which is used for acquiring mammographic images, determining the lesion coordinates, and taking the biopsy.

SUBSTANTIAL EQUIVALENCE

We consider this product modification to be similar in design, composition and function to the following device introduced into commercial distribution after May 28, 1976:

K021945	Planmed Sophie & Sophie Classic (with Digispot and Cytoguide) = Planmed DigiGuide

The biopsy procedure is the same in both systems. Also the needle guidance unit and its control are the same. The main technical difference between the two systems is the detector used. The new system removes 1) the need to move the detector between the stereo exposures, and 2) also the need to mark the reference in the images, making the procedure faster and more accurate.

The nonclinical verification tests made at the factory and accuracy tests conducted by a 3rd party show compliance with set specifications.

The clinical tests were conducted at a mammography screening facility, which already had long experience in using the previous Planmed DigiGuide system. The comparison study included 20 stereotactic biopsies. The end result was that the image quality scored was at least equal with the old system. The new Planmed Nuance DigiGuide system was accurate and reliable in clinical use.

The comparison of characteristics supports substantial equivalence. Planmed Nuance DigiGuide is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

November 21, 2012

Planmed OY
% Mr. Bob Pienkowski
Managing Director
100 North Gary Avenue, Suite A
ROSELLE IL 60172

Re: K121963
Trade/Device Name: Planmed Nuance DigiGuide
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: MUE
Dated: October 12, 2012
Received: October 17, 2012

Dear Mr. Pienkowski:

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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health 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,

Robert A. Ochs

Janine M. Morris
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): K121963

Device Name: Planmed Nuance DigiGuide

Indications for Use:

Planmed Nuance DigiGuide is an optional system for Stereotactic Biopsy. It consists of a needle guidance unit attached to Planmed Nuance or Planmed Nuance Excel digital mammography X-ray units and DigiGuide software module for Nuance Manager 3 acquisition software.

The system is used for needle sampling of women's breast tissues for examination. The use of Planmed Nuance DigiGuide is allowed only under supervision of a health care professional.

Prescription Use __Yes___ 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* Diagnostics and Radiological Health (OIR)

Robert A. Ochs
2012.11.21 10:46:32 -05'00'

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k)_____