

1K973368

GE Medical Systems

P.O. Box 414, W-709
Milwaukee, WI 53201
USA

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

5 September, 1997

OCT 17 1997

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

Contact: Larry A. Kroger, Ph.D.
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Identification of Product

The Strait'Map is an optional accessory consisting of a software program and a grid to provide distortion-free digital x-ray images that can be used in x-ray angiography in stereotactic conditions. It is manufactured by GE Medical Systems - Europe, 283, rue de la Miniere, 78530 BUC, France, and is distributed by GE Medical Systems, Milwaukee, WI.

Device Description

This optional software is run after the acquisition of patient images is completed and has no effect on the acquisitions. Two orthogonal acquisitions are required to obtain accurate localization in the region of interest. The image correction is based on distortion calibration using a straight grid image, with the patient removed from the imaging field. A separate calibration is performed for each patient series to be corrected.

Indications for Use

The Strait'Map is intended to permit digital x-ray systems to produce distortion-free images for stereotaxy without the use of a film changer. Strait'Map corrects the geometric distortion in the digital images caused by the image intensifier. The corrected images are then sent to a laser imager for use in neuro-angiographic examinations requiring the use of a stereotactic frame. The correction procedure can be used in either monoplane or biplane configuration.

Comparison with Predicate

Strait'Map permits the production of image intensified images free of the geometrical distortion which are comparable to those produced by film changers. Strait'Map corrects the distortion caused by the image intensifier in the image chain of digital images to accomplish the same geometrical accuracy as image taken with film changers that do not utilize an image intensifier.

Conclusion

It is the opinion of GE Medical Systems that Strait'Map is safe and potential hazards (less accurate image correction) are controlled by a risk management plan including hazards analysis, software development process, and external evaluation by different hospitals. The use of the Strait'Map option does not change the intended use of the angiographic systems with which it is used.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 1997

Larry A. Kroger, Ph.D.
Regulatory Affairs
Program Manager
GE Medical Systems, Inc.
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Milwaukee, WI 53201

Re: K973368
Strait' Map Option (Angiographic X-Ray System)
Dated: September 5, 1997
Received: September 8, 1997
Regulatory class: II
21 CFR 892.1600/Procode: 90 IZI

Dear Dr. Kroger:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsmamain.html>.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Strait'Map

Indications For Use:

Indications for Use

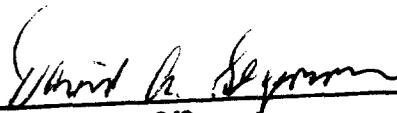
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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801-109)

OR Over-The-Counter Use _____



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973368