K973270

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

August 27, 1997

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

NOV 25 1997

Contact: Larry A. Kroger, Ph.D.
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Identification of the product

The Leg'Map option is a software program intended to provide a high quality full leg x-ray image display of several digital acquisitions on arteries of lower limbs. 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.

Indications for Use

The Leg'Map software is intended for use to combine a series of digital images acquired by diagnostic radiography during a table translation into a single image, such as combining a series of images of the arteries of the lower leg acquired during bolus chasing. Leg'Map provides the convenience of viewing a single image rather than several images. Also, the Leg'Map digital image meets the preference of those who want an image similar to that of the long cut film (30cm x 120cm) previously used when performing this procedure.

Device Description

This optional software is run after image acquisition is completed to provide automatic pasting of multiple images acquired in bolus chasing into a single image. It has no affect on the image acquisition system. Leg'Map process its imager from strips extracted from original images and registered with correlation measurements.

Conclusions

It is the opinion of GE Medical Systems that Leg'Map is safe and potential hazards (wrong pasted images) are controlled by a risk management plan including hazards analysis, software development process, and external evaluation by different hospitals..

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 25 1997

Larry A. Kroger, Ph.D.
Regulatory Affairs
Program Manager
GE Medical Systems, Inc.
P.O. Box 414
Milwaukee, WI 53201

Re: K973270
Advantage Paste: Angiographic Image Combiner
Dated: August 29, 1997
Received: September 2, 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): K973270

Device Name: Leg'Map

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801-109)

OR Over-The-Counter Use_____

David G. Hoyman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973270