K993792

NOV 24 1999

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

Smart Vessel Analysis (SMART VA)

SUMMARY OF SAFETY AND EFFECTIVENESS

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

Identification of Submitter:

Larry A. Kroger, Ph.D.
Senior Regulatory Program Manager
Telephone: (414) 544-3894
Date Prepared: September 3, 1999

Identification of Product:

Name :	Smart Vessel Analysis (Smart VA) Option
Manufacturer :	General Electric Medical Systems 283, rue de la Miniere 78533 Buc Cedex, FRANCE
Distributor :	General Electric Medical Systems, Milwaukee, WI

Marketed Devices:

The Smart VA is substantially equivalent to the devices listed below:

Model:	Advantage Windows 3D (K954355) with Navigator Option and DLX (K926258)
Manufacturer:	General Electric Medical Systems, Buc Cedex, FRANCE

Device Description:

SmartVA is a software post-processing package for the Advantage Workstation (AW) platform. It is an additional tool for the analysis of 3D angiography data providing a number of display, measurement and batch filming/archive features to study user-selected vessels which include but are not limited to stenosis analysis, pre/post stent planning procedures and directional vessel tortuosity visualization.

Application examples include:

° automated batch filming and the ability to rotate around a vessel.
° quantitative information on user-selected vessel segments.
° single reports that provide complete 3D context; measurements; cross-references, and 3D views.
° background auto-filming that replaces manual filming.

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Indications for Use :

Smart Vessel Analysis (SmartVA) is a software post-processing option for the Advantage Workstation (AW) platform, which can be used in the analysis of 3D angiography data. It provides a number of display, measurement and batch filming/archive features and will aid physicians in studying user-selected vessels for stenosis analysis, pre/post stent planning and directional vessel tortuosity visualization.

Comparison with Predicate:

Smart Vessel Analysis (Smart VA) is an additional tool for the analysis of 3D angiography data. The vessel measurements are similar to DLX and the visualization views of the vessel provided are similar to Advantage Windows 3D with Navigator option.

Conclusions :

SmartVA is a software post-processing package for the Advantage Workstation (AW) platform. It is an additional tool for the analysis of 3D angiography data providing a number of display, measurement and batch filming/archive features.

The potential hazards are controlled by a risk management plan including:

- a Hazard Analysis/Risk Management Summary
- a Software Development and Validation Process
- a Software Verification Plan

This product provides images comparable to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 24 1999

General Electric Medical Systems
C/o Reiner Krumme
Division Manager
TUV Rheinland of North America, Inc.
12 Commerce Road
Newtown, CT 06470

Re: K993792
Smart Vessel Analysis (Smart VA) Option
Dated: November 4, 1999
Received: November 9, 1999
Regulatory Class: II
21 CFR 892.1750/Procode: 90 JAK

Dear Mr. Krumme:

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 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). 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 requirements, 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting 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: Smart Vessel Analysis (SmartVA) Option

Indications for Use

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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 ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801-109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K993797