



NOV 4 1998

General Electric Company  
P.O. Box 414, Milwaukee, WI 53201-0414

K 982955

**510(K) SUMMARY OF SAFETY AND EFFECTIVENESS**

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

Identification of Submitter: Larry A. Kroger, Ph.D.  
Senior Regulatory Programs Manager  
GE Medical Systems  
Tel. (414) 544-3894  
Summary prepared: 7 August, 1998

Identification of Product: Silhouette VR

Classification Name: Stationary X-ray System

Manufacturer: GE HuaLun Medical Systems Co., Ltd.  
No. 11 Jiuzhong Road, Jiugong Zone.  
Daxing County, Beijing (100076)  
P.R. China

Device Description: The Silhouette VR consists of an integrated table and tube stand, under-the-table generator and power distribution unit, wall stand, dual focal spot x-ray tube and operator's console.

Indications for Use: The Silhouette VR is indicated for use in generating radiographic images of human anatomy in all general purpose diagnostic procedures. This device is not intended for mammographic applications.

Conformance The Silhouette VR will conform the applicable sections of 21CFR 1020.30 and 1020.31, and UL 2601-1 (which includes IEC 601-1 and UL 187). The Silhouette VR also meets the IEC 601-1-2 standard for EMC.

Conclusions: GE considers the Silhouette VR to be equivalent with other marketed devices with the same indications for use and meeting similar standards.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Larry A. Kroger, Ph.D.  
Senior Regulatory Programs Manager  
GE Medical Systems  
P.O. Box 414, W-709  
Milwaukee, WI 53201Re: K982955  
Silhouette VR  
Dated: August 21, 1998  
Received: August 24, 1998  
Regulatory class: II  
21 CFR 892.1680/Procode: 90 KPR

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 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,

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

STATEMENT OF INTENDED USE

510(k) Number (if known): K982955

Device Name: Silhouette VR

Indications for Use

The Silhouette VR is indicated for use in generating radiographic images of human anatomy in all general purpose diagnostic procedures. This device is not intended for mammographic applications.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  \_\_\_\_\_  
(Per 21 CFR 801-109)

OR Over-The-Counter Use \_\_\_\_\_

David H. Segerson  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K982955