JAN 1 7 2003

510(K) SUMMARY

K023533

Manufacturer:	Barco NV Barcoview Theodoor Sevenslaan 106 8500 Kortrijk Belgium
Submitted By:	Ferguson Medical Consultant to Barco NV
Contact Information:	Phone: +32(0) 56 23 32 11 FAX: +32(0) 56 23 3 74
Classification Name:	System, image processing
Common/Usual Name:	Image display system, medical image workstation, image monitor/display, and others
Proprietary Name:	Barco MeDis 5MP2 Aura
Classification Number:	21 CFR 892.2050/Procode 90LLZ
Substantial Equivalence:	Barco NV Display Systems MeDis 5MP2 Quad-Head Medical Diagnostic Display System (K001748)
Device Description:	The MeDis 5MP2 Aura device is a digital image display system
Intended Use:	The Barco MeDis 5MP2Aura Medical Image Processing System is intended to be used in displaying and viewing digital images for review by trained medical practitioners.
Technological Characteristics:	The Barco MeDis 5MP2 Aura device consists of components to provide high resolution visualization of digital images.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2003

Barco NV
c/o Mr. Frank Ferguson
Official Correspondent
Ferguson Medical
P.O. Box 12038
LA JOLLA CA 92039

Re: K023533
Trade/Device Name: MeDis 5MP2 Aura
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: September 25, 2002
Received: October 21, 2002

Dear Mr. Ferguson:

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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (If known): K023533

Device Name: MeDis 5MP2 Aura

Indications For Use:

The MeDis 5MP2 Aura is intended to be used in displaying and viewing digital images for review and analysis by trained medical practitioners.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K023533

Prescription Use ___XX___ OR Over-The- Counter Use _____
(Per 21 CFR 801.109)