



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY 25 2006

BarcoView MIS Edinburgh
c/o Mr. Jeff D. Rongero
Senior Project Engineer
Underwriters Laboratories, Inc.
12 Laboratory Drive
P.O. Box 13995
RESEARCH TRIANGLE PARK NC 27709-3995

Re: K061326
Trade/Device Name: Voxar 3D Enterprise with CardiaMetrix
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 10, 2006
Received: May 10, 2006

Dear Mr. Rongero:

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 (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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



Protecting and Promoting Public Health

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.

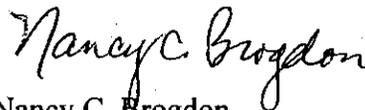
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html>

Sincerely yours,



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

Enclosure

Indications For Use

Applicant:

BarcoView MIS Edinburgh, Bonnington Bond, 2 Anderson Place, Edinburgh, EH6 5NP, UK

510(k) Number (if known):

Unknown

K061326

Device Name:

Voxar 3D Enterprise with CardiaMetrix

Indications For Use:

The Voxar 3D product family is a suite of products that is intended to provide tools for the reading and review of a DICOM compliant series of medical images which can be interpreted as representing a volume of data. These tools are meant for the use of trained medical imaging professionals to aid in their reading and review of such data.

The Voxar 3D product family provides several levels of functionality:

- Basic analysis tools used on a daily basis, such as 2D review, orthogonal Multi Planar Reconstructions (MPRs), oblique MPRs, curved/cross-curved MPRs, slab MPRs, AVEIP, MIP, MiniP, measurements, annotations, reporting, and distribution.
- Tools for in-depth analysis, such as regional segmentation of anatomical structures within the image data, endoscopic review, color volume rendering of finite thickness data cross-sections, 3D review of data volumes, path definition through vascular and other tubular structures, boundary detection, and PET image analysis.
- Specialist tools and workflow enhancements for specific clinical applications which provide directed workflows, custom User Interfaces, and special measurement and reporting functions optimized for the specific clinical applications. Also included are computer-aided detection algorithms which are designed to cue the user on possible structures of interest. Specialized clinical applications include:
 - Colon Screening (which is intended for the screening of patients for colonic polyps, tumours and other lesions using tomographic Colonography),
 - Vessel Analysis (which is intended for the qualitative and quantitative analysis of tomographic angiographic studies to evaluate occlusive and aneurysmal diseases and the effectiveness of stents and stent grafts)
 - Coronary artery analysis (which is intended for the qualitative and quantitative analysis of coronary arteries to evaluate occlusive and aneurysmal disease),
 - Functional cardiac analysis (which is intended to evaluate the functional characteristics of the heart),

Prescription Use X
(21 CFR 801.109)

OR

Over-The-counter Use

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Rita Pally

(Division Sign-Off)

Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number

K061326