DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 9 2006

Mr. Neil Phillips
Quality and Regulatory Manager
BarcoView MIS Edinburgh
Bonnington Bond, 2 Anderson Place
Edinburgh, Lothian, EH6 5NP
UNITED KINGDOM

Re: K060505
Trade/Device Name: Voxar 3D Product Family
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 23, 2006
Received: February 27, 2006

Dear Mr. Phillips:

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.

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

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:

Voxar Ltd, Bonnington Bond, 2 Anderson Place, Edinburgh, EH6 5NP, UK.

510(k) Number (if known): K060505

Unknown

Device Name:

Voxar 3D Product Family

Indications For Use:

The Voxar 3D product family is a suite of products that is intended to provide Physicians, Clinicians and Radiologists with tools to aid them in reading and interpreting DICOM compliant tomographic medical imaging.

The Voxar 3D product family provides several levels of functionality to the user :-

- Basic analysis tools they use 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, distribution, etc
- Tools for in-depth analysis, such as segmentation, endoscopic review, colour VR slab, 3D volume review, path definition and boundary detection, PET imagery analysis, etc
- Specialist tools and workflow enhancements for specific clinical applications which provide targeted workflows, custom UI, targeted measurement and reporting functions including Colon Screening (which is intended for the screening of patients for colonic polyps, tumours and other lesions using tomographic Colonography), Calcium Scoring (which is intended for non-invasive identification and quantification of calcified atherosclerotic plaques in the coronary arteries using tomographic medical image data and clinically accepted calcium scoring algorithms), Vessel Analysis (which is intended for the qualitative and quantitative analysis of tomographic angiographic studies to evaluate occlusive and aneurysmal disease), etc.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David R. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060505

Prescription Use ✓ OR Over-The-counter Use _____
(21 CFR 801.109)