



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 7 2002

Mr. Conrad Chin
Product Director
Voxar Limited
Edinburgh-Corporate Headquarters
Bonnington Bond, 2 Anderson Place
EDINBURGH
EH6 5NP, UK

Re: K012072
Trade/Device Name: Voxar Colonscreen
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications systems
Regulatory Class: II
Product Code: 90 LLZ
Dated: June 28, 2001
Received: July 2, 2001

Dear Mr. Chin:

This letter corrects our substantially equivalent letter of July 12, 2001 regarding the Voxar Colonscreen. The Indications for Use at that time included the phrase "patient screening," which was ambiguous. The ambiguity led to the device's being found substantially equivalent with the agency's having interpreted "patient screening" to mean screening a patient's colon, and not screening a population of patients. You have agreed to amend your Indications for Use to substitute the phrase "patient review" for "patient screening," which is acceptable to the agency. The agency also notes your change of the device's name from Voxar VC to Voxar Colonscreen.

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). 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

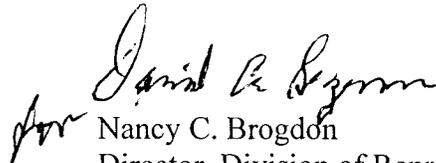
found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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 continue 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 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4654. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Nancy C. Brogdon". The signature is written in a cursive style and is positioned above the typed name.

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

Indications For Use

Applicant:

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

510(k) Number (if known):

K012072

Device Name:

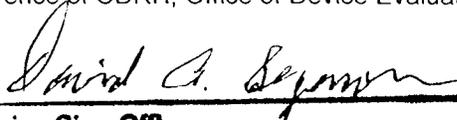
Voxar Colonscreen

Indications For Use:

Voxar Colonscreen is a software application for the display and 3D visualization of medical image data derived from CT and MR scans for the purpose of assisting in patient review and detection of colon polyps, cancers and other lesions by providing display and reporting facilities to enhance workflow. It is intended for use by radiologists, clinicians and referring physicians to process, render, review, store, print and distribute DICOM 3.0 compliant image studies, utilizing standard PC hardware.

(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

K012072

Prescription Use
(21 CFR 801.109)

OR

Over-The-counter Use