NOV - 5 1999

510(k) Summary

K992654

1. Company Identification

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

2. Official Correspondent

Conrad Chin
Head of Engineering

3. Date of Submission

August 6, 1999

4. Device Name

Classification Name	Picture Archiving and Communications System (Image Processing Sub-System) (892.2050)
Common Name	Image processing, management and 3D visualization system
Proprietary Name	Plug 'n View 3D

5. Predicate Device

Pro Vision Diagnostic Workstation (K980648), manufactured by Algotec Systems Ltd.

6. Device Description and Intended Use

Plug 'n View 3D is a software application for the display and 3D visualization of medical image data derived from CT and MRI scans. It is intended for use by radiologists, clinicians and referring physicians to acquire, process, render, review, store, print and distribute DICOM 3.0 compliant image studies, utilizing standard PC hardware.

7. *Substantial Equivalence Comparison Table*

Feature	Plug 'n View 3D	Pro Vision
Computer platform	Pentium MMX, under Windows 95, 98 or NT.	Silicon Graphics O2, under IRIX.
DICOM compliance	DICOM-3 compliance for CT, MRI, NM, CR, SC and Ultrasound (Single Frame) images.	DICOM-3 compliance for CT, MRI, NM, CR, RF and SC images.
2D imaging	• 2D image viewer with real-time window-level, zoom, pan, rotate, flip and cine. • Multiple grid layouts.	Same.
Measurement	2D measurement tools including line, angle and ROI statistics.	Same.
Multi-Planar Reformatting (MPR)	MPR into any user-defined linear plane.	MPR into any user-defined linear or curved plane.
Volume Rendering	Volume rendering with interactive opacity / transparency control, clipping volume of interest (VOI), zoom, pan and rotate.	Same.
Maximum Intensity Projection (MIP)	MIP with interactive window-level, clipping VOI, zoom, pan and rotate.	Same.
Image editing	Tools for removal of obscuring anatomy.	Same.
Printing	Printing to standard Windows printers.	• DICOM printing. • Printing to all major non-DICOM laser imagers.
Ease of use	• Visualization presets. • Semi-automated steps for typical image review procedures.	Customized presets per imaging procedure.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Rob Mackean
Director
Voxar Ltd.
Bonnington Bond
2 Anderson Place
Edinburgh, Scotland
EH6 5NP U.K.

Re: K992654
Plug' n View 3D, Version 1.0
Dated: August 6, 1999
Received: August 9, 1999
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. Mackean:

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 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 (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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
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) K992654

~~Unknown~~

Device Name

Plug 'n View 3D

Indications For Use

Plug 'n View 3D is a software application for the display and 3D visualization of medical image data derived from CT and MRI scans. It is intended for use by radiologists, clinicians and referring physicians to acquire, process, render, review, store, print and distribute DICOM 3.0 compliant image studies, utilizing standard PC hardware.

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K992654

Prescription Use ✓
(Per 21 CFR 801.109)