

2 Summary Of Safety and Effectiveness

This summary of 510(k) safety and Effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

Submitter :

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Name of the Device: Software updates on ProVision.

Predicate Device : ProVision diagnostic Workstation Manufactured by Algotec Systems Ltd.(K954678).

Description of the Device: The ProVision is a multi-modality diagnostic Workstation for processing and archiving radiological images. It is based on off-the shelf Silicon Graphics UNIX based computers that comply with the accepted international standards for computer systems. The systems also comprises software developed and validated by *Algotec Systems Ltd.*

Intended use: The systems is intended for use by radiologists as an interactive tool for analyzing radiological data.

Comparison of Technological Characteristics: The new updates made on the Provision workstation share the same software and hardware backbone as the original applications. They are an inherent part of the workstation and share the identical system resources. The new updates simply provide quicker methods to reach results that would have been time consuming on the previous version of ProVision software.

The addition of these software updates raises no new issues of safety or effectiveness.

February 10, 1998

DR Menashe Benjamin, President

Date

Signature, Title

Menashe Benjamin



JUL 20 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Algotec Systems, LTD
c/o Eli M. Orbach
International Regulatory Consultants
P.O. Box 6718
Efrat 90435
IsraelRe: K980648
ProVision (Diagnostic Workstation)
Dated: May 27, 1998
Received: May 29, 1998
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Dr. Orbach:

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 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (K) Number (if known): K980648

Device Name: ProVision Workstation

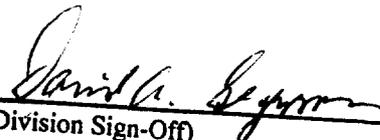
Indications for use:

ProVision is an independent diagnostic viewing and processing workstation. It is based on a Silicon Graphics Workstation running under Unix. ProVision communicates with imaging systems of different modalities (currently CT, MRI, CR, RF, NM) utilizing the DICOM - 3 standard. Connection may also be made to any other DICOM device.

ProVision functions include :Archiving, displaying, manipulation, filming, 2- and 3-dimensional processing. ProVision employs a graphical multi - Window, icon and mouse driven user interface. It is designed to ensure maximum flexibility on the one hand, and intuitive operation on the other.

(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, ENT,
 and Radiological Devices
 510(k) Number K980648

Prescription use X
(Per 21 CFR 801.109)

OR

Over The Counter Use _____
(Optional Format 1-2-96)