NOV 2 5 2003

K033013

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: MediPrime

Predicate Device: This is a Special 510(k) for the MediPrime, a Radiology Reading and Reporting Station, that was cleared under K002894 and K023936.

Description of the Device: The MediPrime is a multi-modality radiology reading and reporting station for viewing and processing radiological images and generating and viewing radiology reports. It is based on off-the shelf PCs running Windows 2000/XP operating systems and a number of monitors (regular or high resolution) that comply with the accepted international standards for computer and monitor systems. The system also comprises software developed and validated by *Algotec Systems Ltd.* The modified device contains added features, including Angiography MIP, Vessel Tracking and Tissue Definition.

Intended Use: The system, that is comprised of diagnostic reading software, is intended for use by radiologists as an interactive tool for analyzing radiological data and generating and viewing radiology reports based on their analysis.

Comparison of Technological Characteristics: The modifications to the MediPrime do not affect the intended use or alter the fundamental scientific technology of the device. The only device modification was to software. There are no labeling changes that affect the intended use of the device. The device modifications raise no new issues of safety or effectiveness.

September 23, 2003

Date

Dr. Menashe Benjamin, President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Algotec Systems, Ltd.
% Dr. Eli M. Orbach
Consultant
International Regulatory Consultants
P.O. Box 6718
Efrat 90435
ISRAEL

Re: K033013
Trade/Device Name: MediPrime
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications systems
Regulatory Class: II
Product Code: 90 LLZ
Dated: September 23, 2003
Received: November 10, 2003

Dear Dr. Orbach:

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 (PMA), 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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

3 Indications For Use (separate page):

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510(k) Number (if known) K033013

Device Name: MediPrime

Indications For Use:

The system, that is comprised of diagnostic reading software, is intended for use by radiologists as an interactive tool for analyzing radiological data and generating and viewing radiology reports based on their analysis.

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033013

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over The Counter Use_____
(Per 21 CFR 801.109)