K031350

ATTACHMENT 7

JUN 23 2003

Summary of Information Respecting Safety And Effectiveness

This 510(K) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

Contact: Vincent J. McGill
Phone: (212) 779-9910
Fax; (212) 779-9928

Product: 3TP Software Option
Imaging Processing Software for MR Devices
Manufactured by: 3TP LLC
Distributed by: 3TP LLC

1) Indications for Use

The 3TP Software Option is intended to be used as a post processing software package designed to provide a reliable means for visualizing the presence and pattern of contrast induced enhancement on MR datasets. 3TP supports the evaluation of dynamic MR data gathered during the injection of a bolus of contrast media. The resulting time course information can be displayed in a variety of formats, including a parametric image overlaid onto source MR images. In the hands of a trained physician the information provided by the 3TP Software Option could yield information that may assist in the interpretation of dynamic contrast enhanced studies.

2) Device Description

The 3TP Software Option is a post processing software module. The 3TP Software Option supports the evaluation of dynamic MR data gathered after the injection of a bolus of a contrast agent. Multi-sliced MR datasets with specified time intervals are used for input. The purpose is to provide a new composite "3TP Image" that provides a trained physician with information useful for diagnostic purposes.

3) Marketing History

The software has not yet been marketed.

4) Predicate Devices

GE Advantage Windows With Functool Option (K960265) GE Medical Systems 300 N. Grandview Blvd. Waukesha, WI 53186	GE Prostate Spectroscopy and Imaging Exam (PROSE) (K011604) GE Medical Systems 300 N. Grandview Blvd. Waukesha, WI 53186	Philips EasyVision (Quantitative Analysis Option) (K971965) Philips Medical Systems 710 Bridgeport Ave Shelton, Ct 06484

Similar to each of the named predicate devices the 3TP Software Option provides a post-processing means for analyzing changes in signal intensity of a contrast agent as reflected in MR images. The use of the 3TP Software Option does not result in any additional hazards when compared to the post-processing software packages (Functyool, PROSE and Philips EasyVision) currently being marketed by GE Medical Systems and Philips Medical Systems. The 3TP Software Option does not include any new indications for use nor does the use of this device result in any new potential hazards.

5. **Performance Testing**

The 3TP Software Option will successfully complete integration testing and verification prior to beta validation and the software beta testing will be successfully completed validating the 3TP Software Option prior to market release.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 2003

3TP LLC
% Mr. Vincent J. McGill
Eaton & Van Winkle, LLP
3 Park Avenue
NEW YORK NY 10016

Re: K031350
Trade/Device Name: 3TP Software Option
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: April 28, 2003
Received: April 29, 2003

Dear Mr. McGill:

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 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

510(k) Number (if known): K 0 3 1 3 5 0

Device Name:

Indications for Use:

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(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 C.F.R. 801.109)

(Optional Format 1-2-96)

David R. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031350