K041022
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JUN 17 2004

ITEM I

510(k) SUMMARY

Safety and Effectiveness

1. Medical Device Establishment:

Syntermed, Inc.
Registration No. 1066019
Owner Operator I.D. 9041128
Voice &FAX: (714) 281-1256
Contact person: Kenneth Van Train
Email: vantrain@syntermed.com
Date Summary Prepared: April 13, 2004

2. Medical Device:

NeuroQ™ - PET DP Program is indicated to:

1) assist with regional assessment of human brain scans, through automated quantification of mean pixel values lying within standardized regions of interest (S-ROI's), and
2) assist with comparisons of the activity in brain regions of individual scans relative to normal activity values found for brain regions in FDG-PET scans, through quantitative and statistical comparisons of S-ROI's.

3. Medical Device Equivalence:

Mirage/Modification to Mirage (NeuroGam™) Ref. 510(k) #'s:K972886 and K010726.

4. Device Description:

The **NeuroQ™ – PET DP** Display and Analysis Program has been developed to aid in the assessment of human brain scans through quantification of mean pixel values lying within standardized regions of interest, and to provide quantified comparisons with brain scans derived from FDG-PET studies of defined groups having no identified neuropsychiatric disease or symptoms, i.e., asymptomatic controls (AC). The Program provides automated analysis of brain PET scans, with output that includes quantification of relative activity in 240 different brain regions, as well as measures of the magnitude and statistical significance with which activity in each region differs from mean activity values of brain regions in the AC database.

This program was developed to run in the IDL operating system environment, which can be executed on any nuclear medicine computer systems which support the IDL software

platform. The program processes the studies automatically, however, user verification of output is required and manual processing capability is provided.

5. Intended Use and Potential Adverse Effect on Health:

The intended use of this program was to provide the physician with a program which would allow him to co-register and display brain PET scans and compare the patients study to a reference database. This program serves merely as a display and processing program to aid in the diagnostic interpretation of a patient's study. It was not meant to replace or eliminate the standard visual analysis of the PET brain scan. The physician should integrate all of the patients' clinical and diagnostic information, i.e. patients' history, quality control images, visual interpretation of the PET brain scan, and quantitative results, prior to making his final interpretation. This comprehensive processing technique (as with all diagnostic imaging) is not perfect, and will be associated with some false positive and false negative results. The expected accuracy of the program can be found in Item H, Testing & Validation and the physician should be aware of the accuracy when integrating the quantitative results for his final interpretation. Therefore, this program has no direct adverse effect on health since the results represent only a part of the information, which the physician will utilize for his final interpretation. The final responsibility for interpretation of the study lies with the physician.

6. Marketing History:

There have been other medical device programs marketed in the past which perform similar functions to those performed by the NeuroQ™ - PET DP program. Most Nuclear Medicine manufacturers have programs that can co-register SPECT/PET data and some of them have programs for comparison of the patient's data to a reference database. NeuroQ™ - PET DP provides a program which executes in the IDL operating system environment and we believe is substantially equivalent to theMirage/Modification to Mirage (NeuroGam™) Ref. 510(k) #'s:K972886 and K010726. To our knowledge there have been no safety problems with the co-registration and comparison to a reference database for the Mirage NeuroGam™ program which has been in the marketplace for over two years.

7. Conclusions:

The safety of this program has been determined through the various stages of software development which included the initial design, coding, debugging, testing, and validation. The effectiveness of the program has been established in in-house testing and clinical validation studies. Specific details and results concerning the validation of the NeuroQ™ - PET DP program are listed in Item H, Testing & Validation. We contend that the method employed for the development and the final in-house validation results of this medical display software program, NeuroQ™ - PET DP, have proven its safety and effectiveness. In our opinion, NeuroQ™ - PET DP program is substantially equivalent to the Mirage NeuroGam™ program which has been cleared for marketing. NeuroQ™ - PET DP program is intended for the same purpose and raises no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2004

Mr. Kenneth F. Van Train
President
Syntermed, Inc.
Tower Place Center
3340 Peachtree Road, NE
Suite 1800
ATLANTA GA 30326

Re: K041022
Trade/Device Name: NeuroQ-PET DP
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: 90 KPS
Dated: April 17, 2004
Received: April 20, 2004

Dear Mr. Van Train:

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

510(k) NUMBER (IF KNOWN): K041022

DEVICE NAME: NeuroQ™ - PET DP

INDICATION FOR USE:

NeuroQ™ - PET DP Program is indicated to:

1) assist with regional assessment of human brain scans, through automated quantification of mean pixel values lying within standardized regions of interest (S-ROI's), and

2) assist with comparisons of the activity in brain regions of individual scans relative to normal activity values found for brain regions in FDG-PET scans, through quantitative and statistical comparisons of S-ROI's.

(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)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041022