OCT 4 - 2004

K042258

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: August 3, 2004

2. Medical Device:

The BP-SPECT™ software program should be used for the display of wall motion and quantification of left and right ventricular function parameters from gated Tc99m blood pool SPECT studies.

3. Medical Device Equivalence:

Northwestern Gated Blood Pool SPECT (NUMUGAS™) Ref. 510(k) #: K020300

4. Device Description:

The BP-SPECT™ is used to display gated wall motion and for quantifying parameters of left and right ventricular function from gated blood pool SPECT studies. These parameters are: ejection fraction, end-diastolic volume, end-systolic volume, stroke volume, maximum and average emptying and filling rates, ejection and filling periods and times, and regional ejection fraction. This program was developed to run in the IDL operating system environment which can be executed on any nuclear medicine computer systems which supports the IDL software development environment. 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 display wall motion and determine measurements of ejection fraction and ventricular volumes from his patient's gated blood pool SPECT study. 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 gated blood pool SPECT study. The physician should integrate all of the patients' clinical and diagnostic information, i.e. patients' history, stress and/or rest EKG, quality control images, visual interpretation of the gated tomographic images, 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 several medical device programs marketed in the past which perform similar functions to those performed by the BP-SPECT™ program. Every Nuclear Medicine manufacturer has programs that can calculate planar gated blood pool and several of them have programs for determining similar quantitative parameters of ejection fraction, end-diastolic volume, end-systolic volume, stroke volume, maximum and average emptying and filling rates, ejection and filling periods and times, and regional ejection fraction. BP-SPECT™ provides a program which executes in the IDL operating system environment and we believe is substantially equivalent to the Northwestern Gated Blood Pool SPECT (NUMUGAS™) program. To our knowledge there have been no safety problems with the calculation of functional parameters from SPECT myocardial perfusion studies for the Northwestern Gated Blood Pool SPECT (NUMUGAS™) program which has been used in clinical settings for over three 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 . BP-SPECT™ 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, . BP-SPECT™ program, have proven its safety and effectiveness. In our opinion the . BP-SPECT™ program is substantially equivalent to the Northwestern Gated Blood Pool SPECT™ program which has been cleared for marketing. The . BP-SPECT™ 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

OCT 4 - 2004

Mr. Kenneth F. Van Train
President
Syntermed, Inc.
245 Owens Drive
ANAHEIM CA 92808

Re: K042258
Trade/Device Name: BP-Spect™
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: 90 KPS
Dated: August 4, 2004
Received: August 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 (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 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 this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act 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): K042258

DEVICE NAME: BP-SPECT™

INDICATION FOR USE:

The BP-SPECT™ software program should be used for the display of wall motion and quantification of left and right ventricular function parameters from gated Tc99m blood pool SPECT studies.

(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)

(Optional Format 1-2-96)

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042258