Syntermed, Inc.                                                                                August 16, 2018
℅ Mr. Kenneth Van Train
President
245 South Owens Drive
ANAHEIM CA  92808

Re:  K180077
     Trade/Device Name:  NeuroQ 3.8
     Regulation Number:  21 CFR 892.1200
     Regulation Name:  Emission computed tomography system
     Regulatory Class:  II
     Product Code:  KPS
     Dated:  July 13, 2018
     Received:  July 20, 2018

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. Although this letter refers to your product as a device, please be aware that
some cleared products may instead be combination products. The 510(k) Premarket Notification Database
located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination
product submissions. 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. Please note:  CDRH does not evaluate information related to contract liability warranties. We
remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for
devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
   and Radiological Health
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number  *(if known)*
K180077

Device Name
NeuroQ 3.8

Indications for Use  *(Describe)*

The NeuroQ™ 3.8 program is used to regionally quantify activity in brain PET and SPECT scans using a ROI count method.  It displays co-registered PET, SPECT and CT images, along with output from quantification of activities reflecting regional concentrations of FDG, amyloid imaging agents, SPECT perfusion and dopamine transporter radiotracers, relative to activities in any of several user-selected reference regions or whole brain.  It provides for displaying and quantifying the regional differences between two PET or SPECT brain studies for the same patient, or the levels of amyloid imaging agents retained in specified brain regions of a patient, and for assisting the user in the examination of brain scans acquired for assessing neurodegenerative processes underlying symptoms of cognitive and movement disorders by comparing regional activity values to each other and to those in brain scans acquired for asymptomatic control subjects. These neurodegenerative processes can be Alzheimer's disease, Lewy body dementia, Parkinson's disease with dementia, vascular dementia, and frontotemporal dementia.

The product is intended for use by trained nuclear technicians and nuclear medicine physicians. The clinician remains ultimately responsible for the final interpretation and diagnosis based on standard practices and visual interpretation of all SPECT and PET data.

Type of Use  *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D)          ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

# Item I

# 510(k) SUMMARY

# Safety and Effectiveness

1. Medical Device Establishment:

Syntermed, Inc.
Registration No. 1066019
Owner Operator I.D. 9041128
Device Regulation Number: 892.1200
Product Code: KPS
Classification Panel: Radiology
Voice:   (888) 263-4446 ext 102,   FAX: (714) 281-1290
Contact person: Kenneth F. Van Train
Address:      Syntermed, Inc.
              130 Wieuca Road
              Suite 108
              Atlanta, GA 30342
Email: vantrain@syntermed.com

Date Summary Prepared: April 5, 2018

2. Medical Device:

Common/Unusual Name: NeuroQ 3.8 – Display and Analysis program for PET Brain studies.

Classification Name – System, Tomography, Computed, Emission

3. Medical Device Equivalence:

- NeuroQ™ 3.6, Reference #: K130451
- Hermes Medical Solutions AB, Hermes Medical Imaging Suite v5.2, Reference #: K121278.
- General Electric Xeleris 4.0 Processing and Review Workstation, Reference #: K153355.

4. Device Description:

**NeuroQ™ 3.8** 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. The program can also be used to compare activity in brain regions of individual scans between two studies from the same patient, between symmetric regions of interest within the brain PET study, to perform an image fusion of the patients PET and CT data, and to provide analysis of amyloid uptake levels in the brain. The program can also be used to provide a quantitative analysis of uptake levels in basal ganglia structures of the brain. 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. <u>Indication for use and Potential Adverse Effect on Health:</u>

The NeuroQ™ 3.8 program is used to regionally quantify activity in brain PET and SPECT scans using a ROI count method. It displays co-registered PET, SPECT and CT images, along with output from quantification of activities reflecting regional concentrations of FDG, amyloid imaging agents, SPECT perfusion and dopamine transporter radiotracers, relative to activities in any of several user-selected reference regions or whole brain. It provides for displaying and quantifying the regional differences between two PET or SPECT brain studies for the same patient, or the levels of amyloid imaging agents retained in specified brain regions of a patient, and for assisting the user in the examination of brain scans acquired for assessing neurodegenerative processes underlying symptoms of cognitive and movement disorders by comparing regional activity values to each other and to those in brain scans acquired for asymptomatic control subjects. These neurodegenerative processes can be Alzheimer's disease, Lewy body dementia, Parkinson's disease with dementia, vascular dementia, and frontotemporal dementia.

The product is intended for use by trained nuclear technicians and nuclear medicine physicians. The clinician remains ultimately responsible for the final interpretation and diagnosis based on standard practices and visual interpretation of all SPECT and PET data.

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. 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.

Cybersecurity

The risks associated with cybersecurity and the NeuroQ™ medical device have been assessed and resolved to a satisfactory level. The risks are associated with the files or images being corrupted by a security breach. There are methods in place to prevent this corruption through MD5 checksums, encryption, multiple patient labels on output screens to allow for patient authentication by users, and using methods for compiling of code and interfaces that substantially reduce or eliminate the ability to corrupt the code. In addition, it is the responsibility of the local information technology personnel at the institution to implement the necessary security methods and procedures to restrict access to the computers and data stored on these systems. Some of these methods include limiting access to trusted users through user ID and passwords, implementing timed methods to terminate sessions, and using strengthen password protection methods. They should also ensure trusted content and implement methods for detection of security compromises and for retention and recovery.

New software versions as well as patches are compiled and moved to a known clean computer and are checked there for viruses and malware. Software is then packaged together into an installer which is signed with a key to ensure the installer remains intact throughout testing and on to distribution.

Validated software updates and patches are provided at least annually and whenever a cybersecurity risk is identified. Notification of availability of these patches is made through the software itself. These updates are delivered as signed installers that present signature information to the user to confirm validity of the source of the patch.

It is always recommended that the installation environment have adequate, updated anti-virus and anti-malware scanners in place. It is also recommended that a firewall, by default, deny all inbound and outbound traffic on the network. At installation time, a list of ports and destinations for firewall exceptions is provided specific to each installation.

6. <u>Marketing History:</u>

There have been other medical device programs marketed in the past which perform similar functions to those performed by the NeuroQ™ 3.8 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™ 3.8 provides a program which executes in the IDL operating system environment and we believe is substantially equivalent to our previous version of NeuroQ™ - PET DP K041022, NeuroQ™ 3.0 (510(k) #: K072307, NeuroQ™ 3.6 (510(k) #: K130451, and Hermes Medical Solutions AB, Hermes Medical Imaging Suite v5.2, Reference K121278. To our knowledge there have been no safety problems with NeuroQ™ - PET DP K041022 which has been in the marketplace since June 2004, NeuroQ™ 3.0 510(k) #: K072307 which has been in the marketplace since March 14, 2008, NeuroQ™ 3.6 510(k) #: K130451 which has been in the marketplace since May 17, 2013, Hermes Medical Solutions AB, Hermes Medical Imaging Suite v5.2, Reference K121278 which has been in the marketplace since December 18,

2012, or General Electric Xeleris 4.0 Processing and Review Workstation, Reference #: K153355 which has been in the marketplace since March 16, 2016.

## 7. Performance Testing Summary

Non-clinical tests:
We have compared the processing and output of the substantially equivalent devices in their literature, web site, and Pre-Market Notification Summaries for Hermes (DATSCAN™) and General Electric (DaTQUANT™). Both of these programs provide similar analysis as the DaTSCAN analysis in NeuroQ v3.8. They all enable visual evaluation and quantification of the DaTSCAN images. They provide a normal database to enable quantification relative to a population of DaTSCAN images without reduced uptake of the dopamine transporter radiotracer (DaTSCAN). All of these medical devices provide a method for automatically defining regions of interest over the left and right basal ganglia and to calculate uptake values for the administered radiopharmaceutical imaging agent (DaTSCAN) in these regions. They all provide analysis of the basal ganglia using the SPECT DaTSCAN imaging agent.

Clinical tests:
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 initial program, NeuroQ™ - PET DP and NeuroQ™ 3.0, has been established in in-house testing and clinical validation studies submitted in our previous 510(k) K041022 and 510(k) #: K072307. The validation for basal ganglia analysis consisted of determining the inter-observer reproducibility of determinations of the scans being without versus with reduced dopamine transporter and the accuracy of the application. Inter-observer reproducibility was highly significant, even between trainee interpreters using the module for quantifying basal ganglia sub regions (e.g., ratios of right posterior putamen to right anterior putamen Pearson coefficient   r=0.59, p=0.00002; ratios of left posterior putamen to left anterior putamen r=0.78, p<0.00001). The sensitivity, specificity, and overall accuracy of quantification-based dichotomized interpretations were all at least 90%.

The results of this validation showed that the analysis of dopamine transporter uptake provides a high accuracy for this analysis and we contend that his validation provides adequate supporting data that this new indication is safe and effective. In addition, we believe that this indication is substantially equivalent to the indications of the predicate devices and is as safe and effective and performs as well as or better than the legally marketed predicate devices,

## 8. 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 initial program, NeuroQ™ - PET DP and NeuroQ™ 3.0, has been established in in-house testing and clinical validation studies submitted in our previous 510(k) K041022, 510(k) #: K072307, and 510(k) #: K130451. Specific details and results

concerning the validation of the NeuroQ™ 3.8 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™ 3.8, have proven its safety and effectiveness.  In our opinion, NeuroQ™ 3.8 program is substantially equivalent to our previous version of NeuroQ™ - PET DP, NeuroQ™ 3.0, NeuroQ™ 3.6 program, Hermes Medical Imaging Suite v5.2, or General Electric Xeleris 4.0 Processing and Review Workstation which have all been cleared for marketing.   NeuroQ™ 3.8 program is intended for the same purpose and raises no new issues of safety or effectiveness.