August 12, 2026

Cortechs Labs, Inc.
Stephen Kosnosky
Dir, Operations and IT
5060 Shoreham Pl.
Suite 240
San Diego, California 92122

Re: K261916
Trade/Device Name: NeuroQuant PET
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: June 8, 2026
Received: June 9, 2026

Dear Stephen Kosnosky:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel M. Krainak, Ph.D.
Assistant Director
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

# Indications for Use

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K261916 |

Please provide the device trade name(s).

NeuroQuant PET

Please provide your Indications for Use below.

NeuroQuant PET aids physicians in the evaluation of patient pathologies via assessment and quantification of PET brain scans.

The software aids in the assessment of human brain PET scans enabling automated analysis through quantification of tracer uptake.

The software generates DICOM PET-MRI and PET-CT fusion images that aid in discerning anatomical patterns of PET tracer uptake. When MRI data is available, the software provides volumetry measurements. NeuroQuant PET is intended to support the clinical interpretation of PET imaging performed for the assessment of cognitive impairment and other neurological conditions.

| | |
|---|---|
| Please select the types of uses. | ☒ Prescription Use (21 CFR 801 Subpart D)<br>☐ Over-The-Counter Use (21 CFR 801 Subpart C) |
| Please select the age group(s) for which the device(s) is to be used. | ☐ Neonates/Newborns (Birth to < 29 days old)<br>☐ Infants (29 days old to < 2 years old)<br>☐ Children (2 years old to < 12 years old)<br>☐ Adolescents (12 years old to < 22 years old)<br>☒ Adults (22 years old and greater) |

# 510(k) Summary: NeuroQuant PET

## 1. Submitter

| | |
|---|---|
| **Name:** | **Cortechs Labs, Inc** |
| **Address:** | 5060 Shoreham Place<br>Suite 240<br>San Diego, CA 92122 |
| **Contact Person:** | Stephen Kosnosky |
| **Telephone Number:** | (858) 459-9700 |
| **E-mail:** | skosnosky@cortechs.ai |
| **Date Prepared:** | June 8 2026 |

## 2. Device

| | |
|---|---|
| **Device Trade Name:** | NeuroQuant PET |
| **Common Name:** | Medical Image Processing Software |
| **Classification Name:** | System, Image Processing, Radiological |
| **Regulation Number:** | 21 CFR 892.2050 |
| **Regulation Description:** | Picture archiving and communications system |
| **Product Code:** | LLZ |
| **Classification Panel:** | Radiology |

## 3. Predicate Device

| | |
|---|---|
| **Device:** | CNeuro cPET |
| **510(k) Number** | K231576 |
| **Manufacturer** | Combinostics Oy |
| **Product Code:** | LLZ, KPS |

## 4. Device Description

NeuroQuant PET is a fully automated post-processing software application designed to assist clinicians in the quantitative analysis of positron emission tomography (PET) imaging data. The device performs automated loading, registration, and quantitative evaluation of PET data acquired with or without accompanying MRI images. NeuroQuant PET supports

PET-MRI, PET-CT, and PET-only workflows. When MRI data is available, the software automatically performs co-registration and PET quantification using FDA-cleared NeuroQuant (K241098) MRI segmented regions and fusion of PET and MRI images to enhance anatomical localization and spatial correspondence for quantification. When MRI is unavailable, a VOI template is transformed into PET native space for quantification.

## 5. Indications for Use

NeuroQuant PET aids physicians in the evaluation of patient pathologies via assessment and quantification of PET brain scans.

The software provides automated analysis and quantification of regional and composite PET SUVR values and centiloid scoring.

The software generates DICOM PET-MRI and PET-CT fusion images that aid in discerning anatomical patterns of PET tracer uptake.

When MRI data is available, the software provides volumetry measurements.

NeuroQuant PET is intended to support the clinical interpretation of PET imaging performed for the assessment of cognitive impairment and other neurological conditions.

## 6. Comparison to Predicate Device

Summary Comparison Table for the device and predicate device (K231576):

| **Device Name** | cNeuro cPET<br>(Predicate, K231576) | **NeuroQuant PET v5.3.0**<br>**(Current Submission)** |
|---|---|---|
| **Classification** | Class II | Class II |
| **Product Code** | LLZ, KPS | LLZ |
| **Indications for Use** | cNeuro cPET aids physicians in the evaluation of patient pathologies via assessment and quantification of PET brain scans.<br>The software aids in the assessment of human brain PET scans enabling automated analysis through quantification of tracer uptake and comparison with the corresponding tracer uptake in normal subjects. The | NeuroQuant PET aids physicians in the evaluation of patient pathologies via assessment and quantification of PET brain scans.<br>The software aids in the assessment of human brain PET scans enabling automated analysis through quantification of tracer uptake. |

| Device Name | cNeuro cPET<br>(Predicate, K231576) | **NeuroQuant PET v5.3.0**<br>**(Current Submission)** |
|---|---|---|
| | resulting quantification is presented using volumes of interest and voxel-based maps of the brain. cNeuro cPET allows the user to generate information regarding relative changes in PET-FDG glucose metabolism.<br>cNeuro cPET additionally allows the user to generate information regarding relative changes in PET brain amyloid load between a subject's images and a normal database, which may be the result of brain neurodegeneration.<br>PET co-registration and fusion display capabilities with MRI allow PET findings to be related to brain anatomy.<br>cNeuro cPET aids physicians in the image interpretation of PET studies conducted on patients being evaluated for cognitive impairment, or other causes of cognitive decline. | The software generates DICOM PET-MRI and PET-CT fusion images that aid in discerning anatomical patterns of PET tracer uptake.<br>When MRI data is available, the software provides volumetry measurements.<br>NeuroQuant PET is intended to support the clinical interpretation of PET imaging performed for the assessment of cognitive impairment and other neurological conditions. |
| **Inputs** | Brain PET/MRI,<br>or PET-only | Brain PET/MRI ,<br>PET/CT,<br>or PET-only |
| **Import of Images** | Upload DICOM files from folder or connectivity to PACS. PET images are mandatory, but MRI images are optional. | Upload DICOM files from folder or connectivity to PACS. PET images are mandatory, but MRI or CT images are optional. |
| **Supported Tracers** | FDG,<br>Flutemetamol,<br>Florbetaben,<br>Florbetapir | Flutemetamol,<br>Florbetaben,<br>Florbetapir |

| Device Name | cNeuro cPET<br>(Predicate, K231576) | **NeuroQuant PET v5.3.0**<br>**(Current Submission)** |
|---|---|---|
| **Output from quantification** | • Regional and composite SUVr<br>• z-scores<br>• For amyloid tracers, results include centiloid score<br>• PET/MR fusion visualizations | • Regional and composite SUVr<br>• For amyloid tracers, results include centiloid score<br>• PET/MR PET/CT fusion visualizations<br>• ROI anatomical overlays<br>• Volumetric measurements of brain structures (with MRI input only) |
| **Method for Quantification** | Fully automated registration to establish the transformation between the PET image and a standard template space. A VOI-template is then transformed to PET native space and is used to quantify tracer uptake.<br>If the patient's MRI is available, this is co-registered with the PET for display purposes, and it is also used during image quantification. | Fully automated registration to establish the transformation between the PET image and a standard template space. A VOI-template is then transformed to PET native space and is used to quantify tracer uptake.<br>If the patient's MRI is available, it is segmented using FDA-cleared NeuroQuant device software and used to quantify tracer uptake after registration to PET native space. |

The proposed NeuroQuant PET application and its predicate device, cNeuro cPET (K231576), are substantially equivalent in their general intended uses, intended users, clinical indications, and principle of operation. Both are post-processing image analysis applications designed for quantitative interpretation of PET data. They share similar design architecture, workflow, and output characteristics.

Both devices are post-processing software applications for analysis of PET imaging data.

Both devices calculate regional and composite PET tracer SUVRs and Centiloid scores.

Both systems incorporate automated analysis using predefined regions of interest to support consistent quantification.

Both devices support PET–MRI fusion for anatomical localization of PET findings when MRI is available.

Both products are intended to aid clinical interpretation of PET imaging in the context of cognitive impairment and other neurological conditions.

## 7. Verification, Validation, and Performance Testing

NeuroQuant PET software was tested in accordance with Cortechs verification and validation (V&V) processes. All product and engineering specifications were verified and validated. Software V&V testing was conducted, and documentation was provided at the documentation level Basic as recommended for premarket submissions for software devices in the FDA's "*Content of Premarket Submission for Device Software Functions*" guidance document.

Verification and Validation tests have been performed to address intended use, the technological characteristics claims, requirement specifications and the risk management results.

The V&V and performance data were provided in support of safety and effectiveness for the substantial equivalence determination.

### 7.1. Verification and Validation Testing Summary

NeuroQuant PET performance is verified and validated using three separate testing methods:

7.1.1. Unit testing to verify components functioning correctly and logs are correctly generated.

7.1.2. System testing to verify that the anatomical overlays, fusion images and reports are correctly generated when PET and compatible anatomical images (when available) are input to NeuroQuant PET and the results meet expectations.

7.1.3. Clinical validation testing that the anatomical overlays, fusion images and reports are produced, meet clinical expectations, and are safe and effective.

V&V activities required to establish performance and functionality of NeuroQuant PET were performed. Testing performed demonstrated that NeuroQuant PET meets all defined functionality requirements and performance claims.

The test results in this 510(k) premarket application demonstrate that NeuroQuant PET complies with the international and FDA-recognized consensus standards and FDA guidance documents listed in the Premarket Submission, meets acceptance criteria, and is adequate for its Intended Use and specifications.

## 8. Performance Testing Summary

NeuroQuant PET performance testing of primary prespecified interest relied for ground truthing on expert-defined putamen and nucleus accumbens regions. Imaging from 14 of 62 available subjects following third-party clinical investigation (NCT00785759) was selected for testing. Performance was quantified in terms of agreement between SUVR estimates paired by subject and region, one estimate derived from the relevant expert-defined regions and the other estimate derived from the matching device-defined regions, given PET-only input. The

percentage of subjects with paired SUVR values differing by more than >0.1 was tested along with the upper and lower bound of the 95% confidence interval (Clopper-Pearson). The percentage of subjects exceeding the threshold ranged from 21% to 29%, with an upper and lower bound percentage range from 51% to 58% and 5% to 8%, respectively. Since neither the tested case selection nor ground truthing methods were device independent, true performance limits may be less favorable than estimated.

Secondary SUVR testing included evaluation of F18 florbetaben and F18 florbetapir NeuroQuant PET post-processing functionality. No notable deviations compared to the primary testing results were identified.

The performance of device Centiloid output depends on SUVR performance and was also tested using clinical datasets published by the Centiloid Project. This testing passed the Project's pre-specified sample-level criteria for investigational site acceptance.

## 9. Conclusions

The performance testing presented above shows that the device is at least as safe, as effective and performs as well as the predicate device.

By virtue of the physical characteristics and intended use, NeuroQuant PET is substantially equivalent to its identified predicate device and its technological improvements do not raise new questions of safety and effectiveness.

END OF DOCUMENT