June 30, 2023

Pixyl SA
% Robert Packard
President
Medical Device Academy Inc.
345 Lincoln Hill Road
SHREWSBURY VT 05738

Re: K213253
Trade/Device Name: Pixyl.Neuro
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: May 26, 2023
Received: May 26, 2023

Dear Robert Packard:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 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
Magnetic Resonance and Nuclear Medicine Team
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213253

Device Name
Pixyl.Neuro

Indications for Use *(Describe)*
Pixyl.Neuro is intended for automatic labeling, visualization and volumetric quantification of segmentable brain structures and lesions from a set of MRI images. Volumetric measurements may be compared to reference percentile 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER

Pixyl SAS
5 Avenue du Grand Sablon
La Tronche, 38700 France
+33 6 19 53 14 48

Contact Person:	Senan Doyle
Date Prepared:	September 29th, 2021

II. DEVICE

Name of Device:	Pixyl.Neuro
Classification Name:	Medical image management and processing system
Regulation:	21 CFR §892.2050
Regulatory Class:	Class II
Product Classification Code:	LLZ

III. PREDICATE DEVICE

Predicate Manufacturer:	CorTechs Labs, Inc
Predicate Trade Name:	NeuroQuant
Predicate 510(k):	K170981

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

Pixyl.Neuro is a software application for the analysis of medical images of the brain. Specifically, the application takes as input MRI images and outputs brain region volumes and lesion volumes in a report format. The application is designed to be used by clinicians treating patients with a range of neurological disorders. The application can be used in the management of patients in a routine setting and in clinical research.

V. INDICATIONS FOR USE

Pixyl.Neuro is intended for automatic labeling, visualization and volumetric quantification of segmentable brain structures and lesions from a set of MRI images. Volumetric measurements may be compared to reference percentile data.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following characteristics were compared between the subject device and the predicate device in order to demonstrate substantial equivalence:

Device	Pixyl.Neuro	NeuroQuant® (K170981)	Comments
Indications for Use	Pixyl.Neuro is intended for automatic labeling, visualization and volumetric quantification of segmentable brain structures and lesions from a set of MRI images. Volumetric measurements may be compared to reference percentile data.	NeuroQuant® is intended for automatic labeling, Visualization and volumetric quantification of segmentable brain structures and lesions from a set of MR images. Volumetric measurements may be compared to reference percentile data.	Substantially equivalent.
Design and Incorporated Technology	• Automated measurement and segmentation of brain tissue volumes and structures	• Automated measurement of brain tissue volumes and structures • Automatic segmentation and quantification of brain structures using a probabilistic neuroanatomical atlas based on the MR image intensity	Input and output data and validation methods are similar, although incorporated technology applied to the segmentation techniques may differ. This does not introduce any additional risk since results are comparable.
Physical characteristics	• Cloud-based software launchable through Picture Archive and Communications Systems (multiple vendors) • Operates on off-the-shelf hardware/platform (multiple vendors)	• Software package • Operates on off-the-shelf hardware (multiple vendors)	Pixyl.Neuro is accessible through users' preferred platforms, directly from their work stations. This does not introduce any additional risk since the use of Pixyl.Neuro is seamlessly integrated into their routine work practice, and does not require any installation or tuning from the end users.
Operating System	Linux	Supports Linux and Mac OS X	Substantially equivalent.
Processing Architecture	Automated internal pipeline that performs: - artifact correction - segmentation - volume calculation - report generation	Automated internal pipeline that performs: - artifact correction - segmentation - volume calculation - report generation	Substantially equivalent.

Data Source	MRI scanner: 2D or 3D FLAIR or T1 MRI scans acquired with specified protocols. Pixyl.Neuro supports DICOM format as input.	MRI scanner: 3D T1 MRI scans acquired with specified protocols • NeuroQuant® Supports DICOM format as input	Pixyl.Neuro supports more options for input MRI sequences. This does not introduce any new risks. Clinical performance evaluation is also performed on these additional inputs.
Output	▪ Provides volumetric measurements of brain structures. ▪ Includes segmented color overlays and morphometric reports ▪ Automatically compares results to reference percentile data and to prior scans when available ▪ Supports DICOM format as output of results that can be displayed on DICOM workstations and Picture Archive and Communications Systems	▪ Provides volumetric measurements of brain structures ▪ Includes segmented color overlays and morphometric reports ▪ Automatically compares results to reference percentile data and to prior scans when available ▪ Supports DICOM format as output of results that can be displayed on DICOM workstations and Picture Archive and Communications Systems	Substantially equivalent.
Safety	• Automated quality control functions: - Tissue contrast check - Scan protocol verification • Results must be reviewed by a trained physician	• Automated quality control functions - Tissue contrast check - Scan protocol verification - Atlas alignment check • Results must be reviewed by a trained physician	Pixyl.Neuro does not perform atlas alignment checks as part of its automated quality control functions. However, the transform used in Pixyl.Neuro's registration step is widely used in neuroimaging as the base step of further image processing. In addition, misalignments are generated on the training dataset for the algorithms to learn the variability of the alignment on the atlases. It has been estimated that this does not introduce any additional risk.

VII. PERFORMANCE DATA

To demonstrate the performance of Pixyl.Neuro, the measured volumes and volume changes of the segmented brain structures are validated for accuracy and reproducibility. The device was tested upon subjects from the following groups: healthy subjects, multiple sclerosis patients, Alzheimer's patients, microangiopathy patients and white matter hyperintensities (of presumed vascular origin) patients.

In the accuracy experiments, the volumes or volume changes are compared to ground truth volumes or volume changes. In the reproducibility experiments, scan / re-scan sessions of the same patients are processed by Pixyl.Neuro and the calculated volumes compared between the two scans. Relevant acceptance criteria have been set based on the results of a literature review for each type of experiment. All experiments passed the acceptance criteria.

The experiments included a total of 238 subject datasets. The segmentation accuracy of Pixyl.Neuro compared to the reference was evaluated using the Dice coefficient metric. The Dice coefficient between the compared measurements is as follows for the different analysis pipelines of Pixyl.Neuro: 0.80 (+/- 0.06) and 0.730 (+/- 0.10) (calculated at the subject level) for MS and FL according to the used testing dataset; 0.84 (+/- 0.02) and 0.83 (+/- 0.02) (averaged Dice scores across the labeled brain structures) for BV according to the used testing dataset. For reproducibility analyses, the mean absolute volume difference between the calculated total lesion volumes from the two scans is: 0.199 ml (+/- 0.193) for the MS and FL modules (total lesion load) and 0.966 ml (+/- 1.098) (mean across de 20 brain structures) for the BV module.

VIII. CONCLUSIONS

The performance testing presented above shows that the device is as safe, as effective and performs as well as the predicate device. By virtue of the physical characteristics and intended use, Pixyl Neuro is substantially equivalent to its predicate device and its technological improvements do not raise new questions of safety and effectiveness.