December 30, 2022

Persyst Development Corporation
Dari Darabbeigi
Vice President of Quality and Regulatory Affairs
420 Stevens Avenue
Suite 210
Solana Beach, California 92075

Re: K222002
Trade/Device Name: Persyst 15 EEG Review and Analysis Software
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OMB, OLT, OMA, OLX
Dated: November 29, 2022
Received: November 30, 2022

Dear Dari Darabbeigi:

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,

Jay R. Gupta -S

Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

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

510(k) Number *(if known)*
K222002

Device Name
Persyst 15 EEG Review and Analysis Software

Indications for Use *(Describe)*

1. Persyst 15 EEG Review and Analysis Software is intended for the review, monitoring and analysis of EEG recordings made by electroencephalogram (EEG) devices to aid neurologists in the assessment of EEG. This device is intended to be used by qualified medical practitioners who will exercise professional judgment in using the information.

2. The Seizure Detection and Seizure Probability component of Persyst 15 is intended to mark previously acquired sections of the adult (greater than or equal to 18 years) EEG recordings that may correspond to electrographic seizures, in order to assist qualified clinical practitioners in the assessment of EEG traces. EEG recordings should be obtained with a full scalp montage according to the standard 10/20 system.

3. The Neonatal Seizure Detection component of Persyst 15 is intended to mark previously acquired sections of neonatal patients' (defined as near-term or term neonates of conceptional age between 36 and 44 weeks and less than two weeks of chronologic age) EEG recordings that may correspond to electrographic seizures, in order to assist qualified clinical practitioners in the assessment of EEG traces. EEG recordings should be obtained with scalp-recorded EEG using the standard International 10-20 system electrode placement, modified for neonates (this includes electrode sites Fp1/2 or alternate F1/2, C3/4, T3/4, O1/2, and Cz, optionally including Fz). Alternatively, the Neonatal Seizure Detection component can operate using a more reduced set of electrodes including C3/4, Fp1/2 (F1/2), and O1/2 (recorded in such a manner to allow creation of montage C3-4, Fp1-O1, Fp2-O2), or an even more simplified electrode set including only C3/4 and Cz (arranged as C3-Cz and C4-Cz), but the three-electrode montage will have decreased sensitivity for seizures due to its limited spatial sampling."

4. The Spike Detection component of Persyst 15 is intended to mark previously acquired sections of the patient's EEG recordings that may correspond to spikes, in order to assist qualified clinical practitioners in the assessment of EEG traces. The Spike Detection component is intended to be used in patients at least one month old. Persyst 15 Spike Detection performance has not been assessed for intracranial recordings.

5. Persyst 15 EEG Review and Analysis Software includes the Persyst Imaging Workflow (PIW), an imaging viewer. It is intended for use by qualified clinical practitioners on both adult and pediatric subjects at least 12 years of age to interpret EEG data in conjunction with any type of neuroimaging including magnetic resonance imaging (MRI) or computed tomography scans (CT). Persyst Imaging Workflow is not intended to provide diagnostic information.

6. The Persyst ESI component of Persyst 15 is intended for use by a trained/qualified EEG technologist or physician on both adult and pediatric subjects at least 3 years of age for the visualization of human brain function by fusing a variety of EEG information with rendered images of an individualized head model and an individualized MRI image.

7.The Persyst 15 sleep state feature provides the user with output concerning wake -sleep states (wake or sleep) present in an EEG recording as an aid in assessing which states are present and when they are present. The EEG being assessed for sleep state should utilize standard 10-20 system electrode recording positions and contain the expected EEG patterns of typical wake and sleep, with no major persistent pathological alterations. The sleep state output is subject to user confirmation via EEG waveform review and is not intended for the diagnosis of sleep disorders (e.g.: sleep apnea, narcolepsy, restless leg syndrome). The sleep state feature is intended for adult and pediatric subjects at least 13 years and older

8. ThePersyst 15 includes the calculation and display of a set of quantitative measures intended to monitor and analyze the

EEG waveform. These include FFT, Rhythmicity, Peak Envelope, Artifact Intensity, Amplitude, Relative Symmetry, and Suppression Ratio. Automatic event marking is not applicable to the quantitative measures. These quantitative EEG measures should always be interpreted in conjunction with review of the original EEG waveforms.

9. The Persyst 15 displays physiological signals, including the calculation and display of a heart rate measurement based on the ECG channel in the EEG recording, which are intended to aid in the analysis of an EEG. Heart rate measurement of Persyst 15 is not applicable to patients with pacemaker and/or active implantable devices.

10. The aEEG functionality included in Persyst 15 is intended to monitor the state of the brain. The automated event marking function of Persyst 15 is not applicable to aEEG.

11. The Persyst 15 provides notifications for seizure detection, quantitative EEG and aEEG that can be used when processing a record during acquisition. These include an on screen display and the optional sending of an email message. Delays of up to several minutes can occur between the beginning of a seizure and when the Persyst 15 notifications will be shown to a user. Persyst 15 notifications cannot be used as a substitute for real time monitoring of the underlying EEG by a trained expert.

12. The Persyst 15 AR (Artifact Reduction) is intended to reduce EMG, eye movement, and electrode artifacts in a standard 10-20 EEG recording. AR does not remove the entire artifact signal, and is not effective for other types of artifacts. AR may modify portions of waveforms representing cerebral activity. Waveforms must still be read by a qualified medical practitioner trained in recognizing artifact, and any interpretation or diagnosis must be made with reference to the original waveforms.

13. This device does not provide any diagnostic conclusion about the patient's condition to the user.

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.

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