December 3, 2025

HippoClinic
% Adam Odeh
CEO
NaviSure Consulting, LLC
PO Box 836032
Richardson, Texas 75083

Re: K251881
Trade/Device Name: HippoMind (v1.0)
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLT, OMA, LLZ, OLY
Dated: July 10, 2025
Received: July 10, 2025

Dear Adam Odeh:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Patrick Antkowiak -S

for
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

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)*
K251881

Device Name
HippoMind (v1.0)

Indications for Use *(Describe)*
HippoMind is a software application that displays neuroimaging and neurosignaling data for review by a health care provider. It provides simple tools for analysis of both medical images and EEG/MEG data. It also allows for storage and transfer of data, and association of data with electronic health records. It is intended for use by qualified health care professionals.

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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510(k) #: K251881

510(k) Summary

Prepared on: 2025-11-03

Contact Details

21 CFR 807.92(a)(1)

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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	HippoMind (v1.0)
Common Name	Electroencephalograph
Classification Name	Amplitude-Integrated Electroencephalograph
Regulation Number	882.1400
Product Code(s)	OLT, OMA, LLZ, OLY

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K200878	Natus Neuroworks	OLT
K172490	eUnity	LLZ
K030737	CTF Whole-Cortex MEG System	OLY

Device Description Summary

21 CFR 807.92(a)(4)

HippoMind is a cloud-based software platform designed for neurologists and neurodiagnostic technologists to review neurophysiological and neuroimaging data. It provides secure, remote access to patient data, through an intuitive interface, to support clinical decision-making.

The platform includes two main modules:

Neurophysiological signal platform: This module enables the review of EEG and MEG data with customizable settings such as amplitude, filtering, and channel templates. It features a labeling system to annotate events, and advanced signal visualization with topological energy graphs. The platform supports Natus EEG, EDF, and CTF MEG formats.

Neuroimaging Review Platform: This module displays 3D MRI, CT, PET, and SPECT images in DICOM or NiFTI format. It offers flexible viewing options, including 3D rendering, customizable color schemes, annotation tools, and an overlay system to superimpose imaging modalities (e.g., TI and T2 images) using affine transformation.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

HippoMind is a software application that displays neuroimaging and neurosignaling data for review by a health care provider. It provides simple tools for analysis of both medical images and EEG/MEG data. It also allows for storage and transfer of data, and association of data with electronic health records. It is intended for use by qualified health care professionals.

Indications for Use Comparison

21 CFR 807.92(a)(5)

HippoMind Neurophysiological Signal Review is not intended for active EEG or MEG monitoring; only for review and analysis of previously collected data. Other indications are the same as the predicates.

HippoMind Neuroimaging Review has no substantial differences in intended use compared to the predicate.

Technological Comparison

21 CFR 807.92(a)(6)

HippoMind Neurophysiological Signal Review does not perform automatic event detection, or any active monitoring. It is otherwise substantially equivalent to the predicate devices.

HippoMind Neuroimaging Review supports fewer modalities than the predicate, and also supports PET and SPECT data. Additionally, NiFTI format is supported. The device is otherwise substantially equivalent to the predicate.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

A usability study was conducted to assess the HippoMind platform's ability to enable neurologists, fellows, residents, and neurodiagnostic technologists to perform tasks related to EEG/MEG and imaging data review. The study involved 15 participants with at least one year of experience in EEG/MEG interpretation, recruited primarily from the University of California - San Francisco. Participants completed assigned tasks including opening and navigating EEG/MEG files, adjusting signal parameters, labeling data, overlaying PET on MRI, and generating reports. Feedback was collected via a questionnaire, with primary and secondary endpoints being the percentage of positive responses (usability score) and comparative scores on efficiency, accessibility, and user-friendliness, respectively.

The primary endpoint showed a high usability score, with 100% positive responses for most tasks. The only exception was one user's failure to label EEG/MEG data. Secondary endpoint scores (1-5 scale, 1 = Strongly agree) averaged ~1.5-2.0, indicating strong agreement on improved efficiency, remote access, learnability, user-friendliness, data loading speed, and report generation.

A confirmatory clinical validation study was conducted to evaluate the HippoMind Neuroimaging and Neurosignaling Platform's performance in displaying and enabling interpretation of medical imaging (MRI, PET, CT, SPECT) and neurosignaling data (EEG, MEG) for epilepsy evaluation and surgical planning.

Three board-certified clinicians participated: two U.S.-licensed neurologists with 37 and 17 years of practice, respectively, and one reviewer from the UCSF MEG Center with 2 years of experience in EEG, MEG, and imaging interpretation.

The study involved 13 patients' imaging data (mean age 42.8, SD 18.6; 6 females, 7 males; diverse ethnicities: 5 Hispanic or Latino, 8 Not Hispanic or Latino; races: 5 Latinx, 4 White, 2 Asian, 1 Southwest Asian and North African, 1 Other) and 10 subjects' MEG data (mean age 59.4, SD 4.5; 5 females, 5 males; all White).

The imaging dataset included 61 images (36 MRI [TI, T2, FLAIR], 9 PET, 10 CT, 6 SPECT), and the neurosignaling dataset included 30 EEG and 20 MEG recordings.

Each clinician independently reviewed the data, answering questions on quality and interpretability:

For EEG/MEG:
(1) Is the signal of good quality?
(2) Can you distinguish between abnormal and normal waveforms?

(3) Is the signal data clinically interpretable?

For images:
(1) Is the image of good quality?
(2) Could you examine all necessary regions of interest?
(3) Does the overlay on T1 or FLAIR look correct? (PET only)
(4) Does the image offer a comparable level of interpretability to the current clinical viewer?

All responses (1,026 total: 270 EEG, 180 MEG, 576 imaging) were "Yes," achieving a 100% pass rate, exceeding the acceptance criteria of 95% positive responses. The platform demonstrated high-quality display and clinical interpretability comparable to existing clinical viewers, with accurate PET overlays and clear visibility of epilepsy-related details.

The non-clinical usability study and clinical validation study support substantial equivalence by confirming the platform's usability, efficiency, and effectiveness for clinical use. The diverse patient demographics, robust clinician agreement, and high usability scores underscore the platform's reliability and user-friendliness across varied data types and user groups.

Comparison of Substantial Equivalence:

Feature	Subject Device	Predicate Device (EEG)	Notes/Comments
	HippoMind (Neurophysiological Signal Review)	*Natus Neuroworks*	*n/a*
510(k) Number	TBD	K200878	n/a
Manufacturer	HippoClinic Inc.	Natus Medical	n/a
Device Class	**Class II**	**Class II**	n/a
Regulation	**882.1400**	**882.1400**	n/a
Product Code	**OLT; OMA**	**OLT; OMA**	n/a
Intended Use/Indications for Use	HippoMind is a software application that **displays** neuroimaging and **neurosignaling** data for review by a health care provider. It provides simple tools for analysis of both medical images and EEG/MEG	Natus NeuroWorks is EEG software that **displays physiological signals**. The intended user of this product is a qualified medical practitioner trained in Electroencephalography who will exercise professional	The intended uses for reviewing are similar. The automatic functions present in Natus Neuroworks do not impact the basic review functions, and raise no issues of safety or effectiveness.

	data. It also allows for storage and transfer of data, and association of data with electronic health records. **It is intended for use by qualified health care professionals.**	judgment in using the information. The Natus NeuroWorks EEG software allows acquisition, display, archive, **review and analysis of** **physiological signals.** • The Seizure Detection component of Natus NeuroWorks 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 full scalp montage	In addition, HippoMind is used solely for reviewing recordings and does not control or modify any acquisition parameters. All parameters, such as recording duration, video and signal synchronization, montages, and sensor names, are automatically adopted from the device software as configured during the original recording. Because HippoMind directly inherits these pre-established parameters without altering them, it introduces **no new risks to safety or effectiveness.**

		according to the standard 10/20 system. • The Spike Detection component of Natus NeuroWorks is intended to mark previously acquired sections of the adult (greater than or equal to 18 years) EEG recordings that may correspond to electrographic spikes, in order to assist qualified clinical practitioners in the assessment of EEG traces. EEG recordings should be obtained with full scalp montage according to the standard 10/20 system. • aEEG, Burst Suppression, Envelope, Alpha variability, Spectral Edge and Spectral Entropy trending functionalities	

		included in Natus NeuroWorks are intended to assist the user while monitoring the state of the brain. The automated event marking function of Natus NeuroWorks is not applicable to these analysis features. • Natus NeuroWorks also includes the display of a quantitative EEG plot, Density Spectral Array (DSA), which is intended to help the user to monitor and analyze the EEG waveform. The automated event marking function of Natus NeuroWorks is not applicable to DSA. • This device does not provide any diagnostic conclusion about the	

		patient's condition to the user.	
Intended Patient Population	**All ages**	**All ages**	
Intended User Population	**Neurologists and Neurodiagnostic technologists**	**Medical professionals**	
Components	Web-based software platform; client-side browser rendering; backend data services**; no hardware.**	Desktop software; integrates with Natus/XLTEK amplifiers; optional video capture; user input via mouse/keyboard; **no standalone hardware in review mode.**	Both are software-only in review mode. Differences in local install versus web-based do not raise any new issues of safety or effectiveness.
EEG Data Source	Pre-acquired EEG files in standard formats; **imported from clinical systems (e.g., Natus .edf); continuous** or epoched.	Acquired via Natus amplifiers or **imported from compatible systems**; **supports .edf** and proprietary formats; **continuous** streaming or stored files	Both support pre-acquired EEG files.
EEG Functions	**Display waveforms; adjustable gain/sensitivity;**	**Display waveforms; gain/sensitivity adjustment;**	Both systems allow for display, filtering, gain adjustment, and

	filtering (bandpass, notch per channel); cropping; **annotations**: lines, boxes, **text labels** for events (**spikes**, **seizures**).	**filtering; annotations**: **text**, markers, event tags; **manual spike/seizure labeling**; detectors for spike/seizure (manual & computer-assisted).	manual annotation. Automatic spike detection is not essential, as spikes can be accurately identified through manual review. The automated detection serves only as an assistive tool, while the final interpretation and annotation must be performed manually by qualified clinicians to ensure accuracy and clinical safety. Differences raise no issues of safety or effectiveness.
Measurements	**Manual measurement tools**: **amplitude**, duration via cursor; no automated quantitative metrics.	**Manual measurements**: **amplitude**, latency; automated trends.	Both support manual amplitude/duration. Automated trends are not a requirement for trend analysis, as this can be observed/performed manually. Differences raise no issues of safety or effectiveness.
Review, Monitor, and Analyze Recordings	**Review stored recordings; scroll/zoom; synchronized video; manual waveform inspection;** distinguish	**Review stored/acquired recordings; scroll/zoom; synchronized video; manual inspection +** optional	Both support scroll/zoom, video sync, manual analysis. Automated functions are indicated as optional.

	normal/abnormal via visual review.	automated event marking (adults); trends to assist brain state monitoring; DSA for EEG waveform analysis.	Differences raise no issues of safety or effectiveness.
Notifications	None.	Optional audio/visual alerts for user-defined DC thresholds; not for life support.	Predicate offers optional alerts. No impact on safety or effectiveness.
Data Storage	Cloud-based secure storage; **local cache; export to standard formats; EHR association.**	**Local/remote disk storage; database archiving; export to .edf or reports.**	Both support secure storage/export. No new issues of safety or effectiveness.
Report Generation	**Customizable reports with waveform screenshots, annotations, images; PDF export.**	**Customizable sleep/EEG report templates** with summaries (counts, averages, max/min, data ranges for trends); **PDF export.**	Both generate custom reports that can be exported. Differences raise no issues of safety or effectiveness.
Performance Validation	**Comparison testing with Natus NeuroWorks: side-by-side review of EEG data.**	**Comparison testing with NicoletOne: side-by-side review of EEG data.**	Both devices performed side-by-side qualitative comparisons of EEG data with the predicate device.

Discussion/Justification:

Natus NeuroWorks is an appropriate predicate for the EEG review and display functions of HippoMind. Both devices share a similar intended use under 21 CFR 882.1400, enabling qualified medical practitioners to review EEG data through manual tools while exercising professional judgment, without providing diagnostic conclusions.

HippoMind's EEG review—-featuring waveform display, adjustable gain/sensitivity, per-channel bandpass and notch filtering, montage creation/modification, time-series cropping, manual annotations (lines, boxes, text for spikes/seizures), and synchronized video—directly corresponds to the review mode of NeuroWorks, which supports equivalent manual capabilities for waveform inspection, gain adjustment, filtering, event tagging, spike/seizure labeling, and video synchronization.

Natus NeuroWorks also offers certain automated analyses, such as for spike detection. However, these functions, while convenient, are not necessary for proper interpretation of EEG data, as all associated analyses can be performed manually. This means that using Natus NeuroWorks in review mode, without any automated analyses, is fully aligned with its FDA clearance, and fully aligned with the proposed HippoMind device’s EEG review functionality.

Furthermore, validation followed the predicate's established approach: NeuroWorks conducted side-by-side comparison testing with NicoletOne, its chosen predicate, confirming identical waveforms, annotations, and filtered traces with no visual distortion. HippoMind replicated this methodology through direct side-by-side comparison with NeuroWorks itself on 30 EEG datasets, where three experienced clinicians achieved 100% agreement on signal quality, temporal/spatial resolution, and spike/seizure visibility. This identical comparison testing confirms that HippoMind's review mode performs equivalently to NeuroWorks' review mode, providing a robust basis for substantial equivalence in EEG functionality.

Feature	Subject Device	Predicate Device (MEG)	Notes/Comments
	HippoMind (Neurophysiological Signal Review)	*CTF Whole-Cortex MEG System*	*n/a*
510(k) Number	TBD	K030737	n/a
Manufacturer	HippoClinic Inc.	CTF Systems, Inc.	n/a
Device Class	**Class II**	**Class II**	n/a
Regulation	**882.1400**	**882.1400**	n/a
Product Code	**OLT; OMA; OLY**	**OLY**	n/a
Intended Use/Indications for Use	HippoMind is a software application that displays neuroimaging and neurosignaling data for review by a health care provider. **It**	<u>Indications for Use:</u> The Omega Whole-Cortex MEG System non-invasively measures the	

	provides simple tools for analysis of both medical images and EEG/MEG data. It also allows for storage and transfer of data, and association of data with electronic health records. It is intended for use by qualified health care professionals.	magnetoencephalographic (MEG) signals (and, optionally, electroencephalographic (EEG) signals) produced by electrically active tissue of the brain. These signals are recorded by a computerized data acquisition system, **displayed, and may then be interpreted by trained physicians** to help localize these active areas. The locations may then be correlated with anatomical information of the brain. MEG is routinely used to identify the locations of visual, auditory, somatosensory, and motor cortex in the brain when used in conjunction with evoked response averaging devices. MEG is also used to non-invasively locate regions of epileptic activity within the brain. The localization information provided by MEG may be used, in conjunction	

		with other diagnostic data, in neurosurgical planning. <u>Intended Use:</u> The Omega Whole-Cortex MEG System is intended for use as a magnetoencephalographic (MEG) device, which non-invasively detects and **displays biomagnetic signals produced by electrically active nerve tissue in the brain.** When interpreted by a trained physician, the data enhances the diagnostic capability by providing useful information about the location relative to brain anatomy of active tissue responsible for critical brain functions.	
Data Input	Accepts pre-existing **MEG data in standard formats (e.g., CTF .ds); supports continuous and epoched**	Processes pre-acquired **MEG data in native CTF .ds format; supports continuous, epoched**, and	Both devices accept pre-acquired CTF .ds MEG data for review. HippoMind supports continuous and

	datasets; timeline continuity maintained within imported files.	pseudo-continuous datasets with .aux reconstruction for full timeline review.	epoched files. While the predicate reconstructs pseudo-continuous timelines via .aux files, HippoMind preserves full timeline continuity within each imported file — the same data reviewed clinically. This difference does not raise new safety/effectiveness questions, as no data loss occurs and users control review segments manually.
Signal Processing	**Adjustable filtering parameters** (bandpass, notch) per channel; access to raw data; cropping of time series into segments.	**Filtering applied to displayed waveforms** (time, frequency, spatial filtering options)	Both devices apply basic filtering to waveforms. No new risks are identified.
Display Features	**Displays MEG waveforms; adjustable amplitude scaling; topological graphs;** standard montages; **sensor-level visualization.**	**Displays MEG waveforms; adjustable amplitude scaling;** sensor-level time series plots; **topological graphs;** headmodel and **sensor visualization**.	Both display MEG waveforms, adjustable amplitude, sensor-level plots, and topological graphs. Headmodel is a diagnostic aid, not required for waveform review.

Analysis Tools	**Annotation tools** (lines, boxes); **manual distinction of abnormal waveforms** (spikes, seizures).	**Annotation tools**; **manual distinction of abnormal waveforms.**	Both devices support manual waveform distinction (spikes/seizures) and annotation tools.
Montage and Channel Management	**Modify or create new montages; select desirable montages; channel selection by name or type.**	**Modify or create new montages; select desirable montages; channel selection by name or type**.	Both devices allow user-defined montage creation/modification and channel selection by name or type.
Output and Reporting	Generate reports with inserted images; **storage and transfer of data; association with EHR.**	**Data storage** at high sample rates; quality assessment**; export for further analysis**; scripting for batch processing.	Both generate clinical review outputs. Storage differences and EHR integration are administrative tasks that do not impact safety or efficacy.

Discussion/Justification:

CTF Whole-Cortex MEG System is an appropriate predicate for the MEG review and display functions of HippoMind, as both are Class II devices under 21 CFR 882.1400 intended for qualified medical practitioners to review pre-acquired neurosignaling data without diagnostic conclusions, emphasizing professional judgment.

HippoMind's MEG review mode—waveform display, adjustable amplitude scaling, per-channel bandpass and notch filtering, topological graphs, standard montages, sensor-level visualization, time-series cropping, and manual annotations (lines, boxes for spikes/seizures),—aligns directly with the software portion of CTF MEG’s review mode.

CTF Whole-Cortex MEG System does contain additional functions related to acquisition of MEG data, but these are out of scope for HippoMind.

Feature	Subject Device	Predicate Device
	HippoMind (Neuroimaging review)	*eUnity*
510(k) Number	TBD	K172490
Manufacturer	HippoClinic Inc.	Client Outlook, Inc.
Device Class	**Class II**	**Class II**
Regulation	**892.2050**	**892.2050**
Product Code	**LLZ**	**LLZ**
Intended Use/indications for use	HippoMind is a software application that **displays neuroimaging** and neurosignaling **data for review by a health care provider**. It provides **simple tools for analysis of** both **medical images** and EEG/MEG data. It also allows for **storage and transfer of data**, and association of data with electronic health records. It is intended for use by qualified health care professionals.	eUnity is a software application that **displays medical image data** and associated clinical reports to aid in diagnosis for healthcare professionals. It performs operations relating to the **transfer, storage, display, and measurement of image data.** eUnity allows users to **perform image manipulations, including window/level, rotation, measurement, and markup. eUnity provides 2D display, Multi-Planar Reformatting and 3D visualization of medical image data,** and mobile access to images. eUnity displays both lossless and lossy compressed images. For lossy images, the medical professional user must determine if the level of loss is acceptable for their purposes. Display monitors or mobile devices used for reading medical images for diagnostic purposes must comply with applicable regulatory approvals and with quality control requirements for their use and maintenance. For mobile diagnostic usage when a full workstation is not available. Mobile use for mammography is for reference and referral only.
Intended Patient Population	**All ages**	**All ages**
Intended User	**Health care professionals**	**Healthcare professionals**
Modality	**MR**, **CT**, PET, SPECT	CR, **CT**, DX, ECG, **MR**, MG, NM, OP, PR, PT, RF, SC, SR, US, XA, VL
Format	**DICOM**, NiFTI	**DICOM**, IHE, Non-DICOM

Feature	Subject Device	Predicate Device
	HippoMind (Neuroimaging review)	*eUnity*
Window Level, Rotate/ Pan/ Zoom, Reset, Presets, Invert	**Yes**	**Yes**
Multi-Study viewing, Image printing, Report Printing, Image Export	**Yes**	**Yes**
Metadata display/hide	**Yes**	**Yes**
Orientation labels, keyboard shortcuts	**Yes**	**Yes**
Measurement tools, Annotation tools (Line, Arrow, Polygon, Freehand, Text)	**Yes**	**Yes**
Full-screen mode, Collaboration, Multimonitor, Linking Series, Revert to Original, Image Sharing, Triangulation, Image scrolling, Layouts, Linked scrolling, Reference lines, Image flip and rotate, Image measurements, Grayscale softcopy presentation states (GSPS)	**Yes**	**Yes**
KIN	**Yes**	**Yes**
Mag lens	**Yes**	**Yes**
Multi-Planar reformat (MPR)	**Yes**	**Yes**
Maximum Intensity Projection	**Yes**	**Yes**
Oblique and double-oblique reformat,	**Yes**	**Yes**

Feature	Subject Device	Predicate Device
	HippoMind (Neuroimaging review)	*eUnity*
Triangulate, Rotate		
3D Volume, orientation widget, Opacity preset, Scalpel Tool, Bone Removal	**Yes**	**Yes**

Discussion/Justification:

eUnity is an appropriate predicate for the neuroimaging functions of HippoMind, as both are Class II devices under 21 CFR 892.2050, and both are intended for use by qualified health care professionals to review pre-acquired imaging data, without diagnostic conclusions, emphasizing professional judgment. Both include basic image analysis tools and are capable of transferring, storing, and displaying images, as is standard for most MIMPS (PACS) systems.

The main difference between eUnity and HippoMind's Neuroimaging platform is that eUnity supports a wider variety of modalities, such as mammography, x-ray angiography, and ultrasound. This reflects eUnity's intended use, which is more general and wider in scope than that of HippoMind. This difference, however, does not present any new risks, as HippoMind is specifically focused on neurological applications, and does not need to support imaging modalities that are primarily used in non-neurological fields.