

Table of New Product Codes and Definitions for 21 CFR 882.1400

Product Code and Name	Definition and Physical State
<p>GWQ full-montage standard electroencephalograph</p>	<p>Acquire, display, store, and archive electroencephalographic signals from the brain using a full montage array (i.e., 16 or more electrodes) and user-specified locations.</p> <p>May include standard electroencephalograph recording hardware (e.g. headbox, cables, computer, monitor, wireless) and basic software (e.g. used to display, store, archive, or manually annotate data). Does NOT include electrodes, more complex software used to analyze electroencephalograph data or automatically detect events, electroencephalograph used for polysomnography or sleep studies, or electroencephalograph with less than 16 electrodes.</p>
<p>OMC reduced-montage standard electroencephalograph</p>	<p>Acquire, display, store, and archive electroencephalographic signals from the brain using a user-specified and/or sponsor-specified locations with a reduced array (i.e., less than 16) of electrodes.</p> <p>May include standard EEG recording hardware (e.g. headbox, cables, CPU, monitor and basic software (needed to display, store and archive EEG and allow user-only annotation and marking); does NOT include electrodes, more complex software used to analyze EEG or automatically detect events, EEG used for PSG or sleep studies, or EEG with > 16 electrodes or more electrodes.</p>
<p>OMA amplitude-integrated electroencephalograph</p>	<p>Measure and record electrical activity of the brain by acquisition of amplitude-integrated electroencephalograph (electroencephalograph signals that have been filtered and displayed in a specific manner).</p> <p>May include standard electroencephalograph recording hardware (e.g. headbox, cables, computer, monitor, wireless) and basic software (e.g. used to display, store, archive, or manually annotate data). Does NOT include electrodes, more complex software used to analyze the amplitude-integrated electroencephalograph signal, software used to automatically detect events, electroencephalograph used for polysomnography or sleep studies, or standard electroencephalograph (full- or reduced- montage).</p>
<p>OLV standard polysomnograph with electroencephalograph</p>	<p>Acquire, display, store, and archive electroencephalographic signals from the brain and other signals (such as electromyography, respiratory and/or oximetry signals) for sleep recordings. May also be used to allow on-screen review, user-controlled annotation and user-controlled marking of data.</p> <p>May include standard polysomnography recording hardware (e.g. headbox, cables, computer, monitor, wireless) and basic software (e.g. used to display, store, archive, or manually annotate data). Does NOT include electrodes, vital signs monitors, polysomnography devices without electroencephalograph, more</p>

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OLY magnetoencephalograph	<p>complex software used to analyze electroencephalograph data or software used to automatically detect events.</p> <p>Acquire, display, store, and archive biomagnetic signals produced by electrically active nerve tissue in the brain to provide information about the location of active nerve tissue responsible for certain brain functions relative to brain anatomy.</p> <p>Magnetoencephalograph recording device (hardware, basic software).</p>
OMB automatic event detection software for full-montage electroencephalograph	<p>Automatically mark or identify electroencephalograph waveforms for spikes, electrographic seizures, seizure-like events in order to aid in identification of such events and help review and annotation of prolonged EEG traces; all output subject to verification by qualified user.</p> <p>Electroencephalograph analysis software. Does NOT include electrodes, electroencephalograph hardware, basic electroencephalograph software (e.g. used to display, store, archive, or manually annotate data), or automatic event detection software used as an intermediary step in source-localization analysis.</p>
ORT burst suppression detection software for electroencephalograph	<p>Automatically mark or identify electroencephalograph waveforms for rhythmic patterns of burst suppression in order to aid in identification of such events and help in the review and annotation of prolonged EEG traces; software can also quantify simple characteristics of the burst suppression such as inter-burst interval or count; all output subject to verification by qualified user.</p> <p>Electroencephalograph analysis software. Does NOT include electrodes, electroencephalograph hardware, basic electroencephalograph software (e.g. used to display, store, archive, or manually annotate data), automatic event (i.e., seizure) detection software or automatic event-detection software used as an intermediary step in source-localization analysis.</p>
OLZ automatic event detection software for polysomnograph with electroencephalograph	<p>Automatically mark electroencephalograph and polysomnograph signals in order to aid in identification of such events and annotation of prolonged PSG traces; automatically calculate simple measures obtained from recorded signals (e.g., magnitude, time, frequency and simple statistical measures of marked events); all output subject to verification by qualified user.</p> <p>Electroencephalograph analysis software. Does NOT include electrodes, electroencephalograph hardware, polysomnograph hardware, or basic electroencephalograph/ polysomnograph software (e.g. used to display, store, archive, or manually annotate data).</p> <p>Uses software algorithms to analyze electroencephalograph and polysomnograph waveforms and automatically</p>

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	identify areas of interest to the user.
OLT non-normalizing quantitative electroencephalograph software	<p>Analyze electroencephalograph data using conventional methodology to output and display standard electroencephalograph parameters for interpretation by a qualified user.</p> <p>Electroencephalograph analysis software. Does NOT include electrodes, amplitude-integrated electroencephalograph, automatic event-detection software, software that compares data to a database (normal or otherwise) or electroencephalograph software that outputs an index, classification, diagnosis, or any clinical interpretation of the data.</p>
OLU normalizing quantitative electroencephalograph software	<p>Post-hoc statistical analysis of electroencephalograph signals with comparison to a normative database for interpretation by a qualified user.</p> <p>Electroencephalograph analysis software. Does NOT include electrodes, amplitude-integrated electroencephalograph, automatic event-detection software, software that compares data to non-normative databases, software that does not compare to a normative database or electroencephalograph software that outputs an Index, classification, diagnosis or any clinical interpretation of the data.</p>
OLW index-generating electroencephalograph software	<p>Analyze electrical activity of the brain by transformation of electroencephalograph signals into a dimensionless index number for use and interpretation by a qualified user.</p> <p>Electroencephalograph analysis software, either developed by 510(k) holder for use in their own hardware or licensed from another company for use in 510(k) holder's hardware. Does NOT include electrodes, amplitude-integrated electroencephalograph, automatic event-detection software, electroencephalograph software with comparative databases (normal or otherwise) or electroencephalograph software that outputs a diagnosis or classification.</p>
OLX source localization software for electroencephalograph or magnetoencephalograph	<p>Correlation of electrical activity of the brain using various neuroimaging modalities for source-localization.</p> <p>Software algorithm. Does NOT include electrodes, amplitude-integrated electroencephalograph, automatic event-detection software used as the only or final electroencephalograph analysis step, electroencephalograph software with comparative databases (normal or otherwise) or electroencephalograph software that outputs an index, diagnosis, or classification.</p>

