January 22, 2025

Natus Neurology Incorporated
Judy Samson
Regulatory Affairs Specialist
3150 Pleasant View Road
Middleton, Wisconsin 53562

Re: K243982
Trade/Device Name: Nicolet EDX
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked Response Electrical Stimulator
Regulatory Class: Class II
Product Code: GWF, IKN, JXE, GWJ, GWE, GZP, OLT
Dated: December 17, 2024
Received: December 23, 2024

Dear Judy Samson:

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,

FDA 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

Device Name

Nicolet EDX

Indications for Use *(Describe)*

The Nicolet EDX is intended for the acquisition, display, analysis, storage, reporting, and management of electrophysiological information from the human nervous and muscular systems including Nerve Conduction (NCS), Electromyography (EMG), Evoked Potentials (EP), Autonomic Responses and Intra-Operative Monitoring including Electroencephalography (EEG).

Evoked Potentials (EP) includes Visual Evoked Potentials (VEP), Auditory Evoked Potentials (AEP), Somatosensory Evoked Potentials (SEP), Electroretinography (ERG), Electrooculography (EOG), P300, Motor Evoked Potentials (MEP) and Contingent Negative Variation (CNV). The Nicolet EDX with Natus Elite Software may be used to determine autonomic responses to physiologic stimuli by measuring the change in electrical resistance between two electrodes (Galvanic Skin Response and Sympathetic Skin Response). Autonomic testing also includes assessment of RR Interval variability. The Nicolet EDX with Natus Elite Software is used to detect the physiologic function of the nervous system, for the location of neural structures during surgery, and to support the diagnosis of neuromuscular disease or condition.

The listed modalities do include overlap in functionality. In general, Nerve Conduction Studies measure the electrical responses of the nerve; Electromyography measures the electrical activity of the muscle and Evoked Potentials measure electrical activity from the Central Nervous System.

The Nicolet EDX with Natus Elite Software is intended to be used by a qualified healthcare provider.

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.

510(K) Summary

Submitted By: Natus Neurology Incorporated
3150 Pleasant View Road,
Middleton,
Wisconsin,
USA 53562

Contact Person: Judy Samson
Regulatory Affairs Specialist
Tel: +1 800 387-7516
E-Mail: judy.samson@natus.com

Proprietary Name: Nicolet EDX

Common Name: Diagnostic Electromyograph

Device Class: Class II

Classification Name: Evoked Response Electrical Stimulator
21 CFR 882.1870

Product Codes

GWF	(Primary)
JXE	
IKN	
OLT	
GWJ	
GWE	
GZP	

Predicate Devices:

K120979	Carefusion Nicolet EDX with Synergy Software
K243495	Natus UltraPro S100

Device Description:

The Nicolet EDX system is designed for the acquisition, display, analysis, reporting, and management of electrophysiological information from the human nervous and muscular systems. The system is designed to perform Nerve Conduction (NCS), Electromyography (EMG), Evoked Potentials (EP), and Autonomic Responses. Nicolet EDX system provides a variety of tests spanning the various modalities.

The Nicolet EDX system consists of the following major components:

- Base unit
- Amplifier (2- or 8-channel)
- Control panels
- Computer- laptop or desktop (with display, keyboard and mouse)
- Display Monitor (for desktop system)
- Application Software (Natus Elite)

The Nicolet EDX optional accessories/ components consist of the following:

- Audio stimulators (Headphones or other auditory transducers)
- Visual stimulators (Natus Visual Stimulator, LED goggles or stimulus monitor)
- Electrical stimulators (RS10 comfort probe, WR50 comfort probe plus)
- Cart and associated accessories (such as arms, mounts and isolation transformer
- Miscellaneous options and accessories such as Patient Response button, Single/Triple footswitch, Tendon (Reflex) hammer, Natus photic stimulator, temperature probe, ultrasound device, bone conductor, printer, etc.

The electrodiagnostics system is powered by a connection to mains.

The entire user interface of Nicolet EDX system consists of two major elements:

- The primary means to interact with the system is via a personal computer (PC) running Natus Elite.
- The second means of interaction is the user interface elements on the hardware.

The Nicolet EDX is intended to be used by a qualified healthcare provider. This device does not provide any diagnostic conclusion about the patient's condition to the user. The intended use environment is in a professional healthcare facility environment.

Indications for Use:

The Nicolet EDX is intended for the acquisition, display, analysis, storage, reporting, and management of electrophysiological information from the human nervous and muscular systems including Nerve Conduction (NCS), Electromyography (EMG), Evoked Potentials (EP), Autonomic Responses and Intra-Operative Monitoring including Electroencephalography (EEG).

Evoked Potentials (EP) includes Visual Evoked Potentials (VEP), Auditory Evoked Potentials (AEP), Somatosensory Evoked Potentials (SEP), Electroretinography (ERG), Electrooculography (EOG), P300, Motor Evoked Potentials (MEP) and Contingent Negative Variation (CNV). The Nicolet EDX with Natus Elite Software may be used to determine autonomic responses to physiologic stimuli by measuring the change in electrical resistance between two electrodes (Galvanic Skin Response and Sympathetic Skin Response). Autonomic testing also includes assessment of RR Interval variability. The Nicolet EDX with Natus Elite Software is used to detect the physiologic function of the nervous system, for the location of neural structures during surgery, and to support the diagnosis of neuromuscular disease or condition.

The listed modalities do include overlap in functionality. In general, Nerve Conduction Studies measure the electrical responses of the nerve; Electromyography measures the electrical activity of the muscle and Evoked Potentials measure electrical activity from the Central Nervous System.

The Nicolet EDX with Natus Elite Software is intended to be used by a qualified healthcare provider.

Summary of Technological Characteristics Compared to the Predicate Devices:

The Indications for use has remained unchanged from the primary predicate.

1. General				
	This submission	Primary Predicate	Reference Predicate	Discussion of differences
Characteristics	Natus Neurology Inc. Nicolet EDX	Natus Neurology Inc. Nicolet EDX (K120979)	Natus Neurology Inc. UltraPro S100 (K243495)	N/A
Product Code	GWF, IKN	GWF	GWF	Identical to predicate.
1.1 Indications for Use	The Nicolet EDX is intended for the acquisition, display, analysis, storage, reporting, and management of electrophysiological information from the human nervous and muscular systems including Nerve Conduction (NCS), Electromyography (EMG), Evoked Potentials (EP), Autonomic Responses and Intra-Operative Monitoring including Electroencephalography (EEG). Evoked Potentials (EP) includes Visual Evoked Potentials (VEP), Auditory Evoked Potentials (AEP), Somatosensory Evoked Potentials (SEP), Electroretinography (ERG), Electrooculography (EOG), P300, Motor Evoked Potentials (MEP) and Contingent Negative Variation (CNV). The Nicolet EDX may be used to determine autonomic responses to physiologic stimuli by measuring the change in electrical resistance between two electrodes (Galvanic Skin Response and Sympathetic Skin Response). Autonomic testing also includes assessment of RR Interval variability. The Nicolet EDX with	The Nicolet EDX is intended for the acquisition, display, analysis, storage, reporting, and management of electrophysiologic information from the human nervous and muscular systems including Nerve Conduction (NCS), Electromyography (EMG), Evoked Potentials (EP), Autonomic Responses and Intra-Operative monitoring including Electroencephalography (EEG). Evoked Potentials (EP) includes Visual Evoked Potentials (VEP), Auditory Evoked Potentials (AEP), Somatosensory Evoked Potentials (SEP), Electroretinography (ERG), Electrooculography (EOG), P300, Motor Evoked Potentials (MEP) and Contingent Negative Variation (CNV). The Nicolet EDX may be used to determine autonomic responses to physiologic stimuli by measuring the change in electrical resistance between two electrodes (Galvanic Skin Response and Sympathetic Skin Response). Autonomic testing also includes assessment of RR Interval variability. The Nicolet EDX with	The UltraPro S100 is intended for the acquisition, display, analysis, storage, reporting, and management of electrophysiological information from the human nervous and muscular systems including Nerve Conduction (NCS), Electromyography (EMG), Evoked Potentials (EP), Autonomic Responses and Intra-Operative Monitoring including Electroencephalography (EEG). Evoked Potentials (EP) includes Visual Evoked Potentials (VEP), Auditory Evoked Potentials (AEP), Somatosensory Evoked Potentials (SEP), Electroretinography (ERG), Electrooculography (EOG), P300, Motor Evoked Potentials (MEP) and Contingent Negative Variation (CNV). The UltraPro S100 may be used to determine autonomic responses to physiologic stimuli by measuring the change in electrical resistance between two electrodes (Galvanic Skin Response and Sympathetic Skin Response). Autonomic testing also includes assessment of RR Interval variability.	Identical to predicate.

	Natus Elite Software is used to detect the physiologic function of the nervous system, for the location of neural structures during surgery, and to support the diagnosis of neuromuscular disease or condition. The listed modalities do include overlap in functionality. In general, Nerve Conduction Studies measure the electrical responses of the nerve; Electromyography measures the electrical activity of the muscle and Evoked Potentials measure electrical activity from the Central Nervous System. The Nicolet EDX with Natus Elite Software is intended to be used by a qualified healthcare provider.	Synergy software is used to detect the physiologic function of the nervous system, for the location of neural structures during surgery, and to support the diagnosis of neuromuscular disease or condition. The listed modalities do include overlap in functionality. In general, Nerve Conduction Studies measure the electrical responses of the nerve, Electromyography measures the electrical activity of the muscle and Evoked Potentials measure electrical activity from the Central Nervous System. The Nicolet EDX with Synergy Software is intended to be used by a qualified healthcare provider.	The UltraPro is used to detect the physiologic function of the nervous system, for the location of neural structures during surgery, and to support the diagnosis of neuromuscular disease or condition. The listed modalities do include overlap in functionality. In general, Nerve Conduction Studies measure the electrical responses of the nerve; Electromyography measures the electrical activity of the muscle and Evoked Potentials measure electrical activity from the Central Nervous System. The Natus UltraPro S100 with Natus Elite Software is intended to be used by a qualified healthcare provider.	
1.2 Warnings	Items related to off label use or misuse.	Items related to off label use or misuse.	Items related to off label use or misuse.	Identical to predicate
1.3 Contraindications	Items related to design and indicated use limitations, such as, not for use in the presence of flammable anesthetics or in conjunction with defibrillation equipment.	Items related to design and indicated use limitations, such as, not for use in the presence of flammable anesthetics or in conjunction with defibrillation equipment.	Items related to design and indicated use limitations, such as, not for use in the presence of flammable anesthetics or in conjunction with defibrillation equipment.	Identical to predicate
1.4 Target Population	Patients with neuromuscular diseases for pediatric and adult patients	Patients with neuromuscular diseases for pediatric and adult patients	Patients with neuromuscular diseases for pediatric and adult patients	Identical to predicate
1.5 Environment of Use	In a professional healthcare facility environment.	In a professional healthcare facility environment.	In a professional healthcare facility environment.	Identical to predicate
2. General Design				
2.1 General Systems Approach	Computer based equipment with dedicated hardware peripherals / components.	Computer based equipment with dedicated hardware peripherals / components.	Computer-based equipment with dedicated hardware peripherals /components.	Identical to predicate
2.2 User Input Device	Windows mouse/keyboard driven graphic interface with dedicated control panel.	Windows mouse/keyboard driven graphic interface with dedicated control panel.	Windows mouse/keyboard driven graphic interface with dedicated control panel.	Identical to predicate
2.3 User Output Device	Digital color display and commercial printers.	Digital color display and commercial printers.	Digital color display and commercial printers.	Identical to predicate

2.4 Patient Inputs	1 to 8 channel amplifier, isolated	1 to 8 channel amplifier, isolated	1 to 4 channel amplifier, isolated	Identical to primary predicate. Similar to reference predicate.
2.5 Signal Acquisition	Analog to digital conversion at 48 kHz per sample rate	Analog to digital conversion at 48 kHz per sample rate	Analog to digital conversion at 48 kHz per sample rate	Identical to primary predicate.
2.6 Trigger Input (synchronization to external events).	Yes	Yes	Yes	Identical to predicate
2.7 Trigger Output (synchronization for external devices)	Yes	Yes	Yes	Identical to predicate
2.8 Footswitch	Yes	Yes	Yes	Identical to predicate
2.9 Use of standard software platform (Operating System)	Yes, Microsoft Windows	Yes, Microsoft Windows	Yes, Microsoft Windows	Identical to predicate
2.10 Customization of protocols	Via storage / retrieval of user defined settings	Via storage / retrieval of user defined settings	Via storage / retrieval of user defined settings	Identical to predicate
2.11 Application flexibility / expandability	Via software update	Via software update	Via software update	Identical to predicate
2.12 Patient circuitry isolation	Optic/transformer	Optic/transformer	Optic/transformer	Identical to predicate
2.13 System Components	EDX base console including 2 electrical stimulators, auditory stimulator, trigger input/output, LED goggle interface; Control panel; Amplifier; Computer, monitor, keyboard, mouse, printer	EDX base console including 2 electrical stimulators, auditory stimulator, trigger input/output, LED goggle interface; Control panel; Amplifier; Computer, monitor, keyboard, mouse, printer	Base console including One electrical stimulator, auditory stimulators, trigger input/output, LED goggle interface; Control panel (integrated); Amplifier; Computer; Monitor; Keyboard; Mouse; Printer	Identical to predicate. Similar to the reference predicate.
2.14 System computer interface	USB	USB	USB	Identical to predicate

2.15 System power supply	Mains (100 -240VAC) thru an isolation transformer depending on system configuration	Mains (100 -240VAC) thru an isolation transformer depending on system configuration	Mains (100 -240VAC) thru an isolation transformer depending on system configuration	Identical to predicate
3. Design – Acquisition				
3.1 Number of channels	1 to 8	1 to 8	1 to 4	Identical to primary predicate. Similar to reference predicate.
3.2 CMRR	>110 Db, 115db typical	>110 dB, 115db typical	>120 dB	Identical to primary predicate. Similar to reference predicate.
3.3 Noise	<0.6 uV RMS (from 2Hz to 10kHz)	<0.6 uV RMS (from 2Hz to 10kHz)	<0.4 uV RMS (from 2Hz to 10kHz)	Identical to primary predicate. Similar to reference predicate.
3.4 Input Impedance	>1000 MΩ	>1000 MΩ	>1000 MΩ	Identical to primary predicate.
3.5 Low Filter	0.05 Hz to 5 kHz	0.05 Hz to 5 kHz	0.05 Hz to 5 kHz	Identical to primary predicate.
3.6 High Filter	30 Hz to 20 kHz	30 Hz to 20 kHz	30 Hz to 20 kHz	Identical to predicate.
3.7 Notch Filter	50/60 selectable	50/60 selectable	50/60 selectable	Identical to primary predicate.
3.8 A/D conversion	24 bit	24 bit	24 bit	Identical to primary predicate.
3.9 Sampling rate (cumulative)	384 kHz	384 kHz	192 kHz	Identical to primary predicate. Similar to reference predicate.
3.10 Trigger mode	Free-run, internal, external	Free-run, internal, external	Free-run, internal, external	Identical to primary predicate. Similar to reference predicate.
3.11 Signal delay (pre/post)	--90% to +90% of sweep, depending on time base	--90% to +90% of sweep, depending on time base	-90% to +90% of sweep, depending on time base	Identical to primary predicate.
3.12 Impedance meter	500Ω to 480 kΩ	500Ω to 480 kΩ	1kΩ to 1,000 kΩ	Identical to primary predicate. Similar to reference predicate.
4. Design – Stimulators				
4.1 Electrical Stimulator				
4.1.1 Type	Constant Current or Constant Voltage	Constant Current or Constant Voltage	Constant Current	Identical to primary predicate. Similar to reference predicate.

4.1.2 Number	1 or 2	1 or 2	1	Identical to primary predicate. Similar to reference predicate.
4.1.3 Maximum Output	100mA or 400V	100mA or 400V	100mA	Identical to primary predicate. Similar to reference predicate.
4.1.4 Duration	0.01 to 1 ms	0.01 to 1 ms	0.01 to 1 ms	Identical to primary predicate..
4.1.5 Mode	Single or Train	Single or Train	Single or Train	Identical to primary predicate.
4.1.6 Biphasic	Yes	Yes	Yes	Identical to primary predicate..
4.2 Auditory Stimulator				
4.2.1 Type	Click, Pip, Burst	Click, Pip, Burst	Click, Pip, Burst	Identical to primary predicate.
4.2.2 Intensity	0 to 139 dB pSPL	0 to 139 dB pSPL	0 to 139 dB pSPL	Identical to primary predicate.
4.2.3 Polarity	Condensation, Rarefaction, Alternating	Condensation, Rarefaction, Alternating	Condensation, Rarefaction, Alternating	Identical to primary predicate.
4.2.4 Tone Frequency	125 to 8000 Hz	125 to 8000 Hz	125 to 8000 Hz	Identical to primary predicate..
4.2.5 Click Duration	0.05 to 1 ms	0.05 to 1 ms	0.05 to 1 ms	Identical to primary predicate.
4.2.6 Side	Left, Right, Both	Left, Right, Both	Left, Right, Both	Identical to primary predicate.
4.2.7 Transducers	Ear Phones, Inserts, Bone Vibrator	Ear Phones, Inserts, Bone Vibrator	Ear Phones, Inserts, Bone Vibrator	Identical to predicate.
4.3 Visual Stimulator				
4.3.1 LED Goggles	Yes	Yes	Yes	Identical to predicate
5. EMG Application Modules				
5.1 Free Run Acquisition	Yes	Yes	Yes	Identical to predicate
5.2 Nerve Conduction Study (NCS)	Yes	Yes	Yes	Identical to predicate
5.3 Stimulator Triggered	Yes	Yes	Yes	Identical to predicate

5.4 Signal Triggered Acquisition	Yes	Yes	Yes	Identical to predicate
5.5 Spontaneous Activity (SPA)	Yes	Yes	Yes	Identical to predicate
5.6 Single Fiber EMG (SFEMG)	Yes	Yes	Yes	Identical to predicate
5.7 Motor Unit Analysis	Yes	Yes	Yes	Identical to predicate
5.8 F-Wave	Yes	Yes	Yes	Identical to predicate
5.9 H Reflex	Yes	Yes	Yes	Identical to predicate
5.10 Sympathetic Skin Response (SSR)	Yes	Yes	Yes	Identical to predicate
5.11 RR Interval Variability	Yes	Yes	Yes	Identical to predicate
5.12 Repetitive Nerve Stim	Yes	Yes	Yes	Identical to predicate
6. Evoked Potential Application Modules				
6.1 Somatosensory EP (SEP)	Yes	Yes	Yes	Identical to predicate
6.2 Auditory EP (AEP)	Yes	Yes	Yes	Identical to predicate
6.3 Visual EP (VEP)	Yes	Yes	Yes	Identical to predicate
6.4 P300	Yes	Yes	Yes	Identical to predicate
6.5 ERG	Yes	Yes	Yes	Identical to primary predicate.
6.6 EOG	Yes	Yes	Yes	Identical to primary predicate.
6.7 CNV	Yes	Yes	Yes	Identical to primary predicate.
7. Other Application Modules.				
7.1 Multi-modality IONM / IOM	Yes	Yes	Yes	Identical to primary predicate.
7.2 EEG	Yes	Yes	Yes	Identical to primary predicate.

7.3 MEP	Yes	Yes	Yes	Identical to primary predicate.
8. Additional Features				
8.1 Automatic Report Narrative Generation	Yes	Yes	Yes	Identical to primary predicate.
8.2 Electrical Stimulus Automation	Yes	Yes	Yes	Identical to primary predicate.
9. Image Display and Control Interface				
9.1 Display and control of noninvasive third party imaging modality (example: Ultrasound)	Yes Integrated (concurrent) ultrasound display and control using the Sonoscanner Ultrasound System (K232285) with Natus Elite software.	No Supports ultrasound by supplying a third-party device which operates in a nonintegrated mode. Using the Sonoscanner Ultrasound System (K232285)	Yes Integrated (concurrent) ultrasound display and control using the Sonoscanner Ultrasound System (K232285) with Natus Elite software.	Identical to reference predicate.

Conclusion:

Verification and validation activities were conducted to establish the performance and safety characteristics of the Nicolet EDX. The results of these activities demonstrate that the Nicolet EDX is safe, effective, and performance is substantially equivalent to the predicate devices.