



September 24, 2026

inomed Medizintechnik GmbH
Johannes Hoerth
Regulatory Affairs Manager
Im Hausgruen 29
Emmendingen, BW 79312
Germany

Re: K263010

Trade/Device Name: ISIS Headboxes, ISIS Neurostimulator, ISIS Xpert Plus, ISIS Xpert, ISIS Xpress
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked Response Electrical Stimulator
Regulatory Class: Class II
Product Code: GWF, GWE, GWJ, GWQ, ETN, IKN
Dated: August 28, 2026
Received: August 28, 2026

Dear Johannes Hoerth:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Patrick Antkowiak
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

510(k) Number (if known)

K263010

Device Name

ISIS Headboxes, ISIS Neurostimulator, ISIS Xpert Plus, ISIS Xpert, ISIS Xpress

Indications for Use (Describe)

Indications for Use: The product is used for intraoperative monitoring and testing during surgical procedures to examine neuronal tissue (central and peripheral nervous system) by recording and stimulation.

The product can be used during surgical procedures that justify non-therapeutic clinical use of the following modalities or their combinations:

• Measurement:

- Auditory evoked potentials (AEP)
- Electroencephalography (EEG)
- Electrocorticography (ECoG)
- Electromyography (EMG)
- Somatosensory evoked potentials (SSEP)
- Motor evoked potentials (MEP)
- Visual evoked potentials (VEP)
- Train of Four (TOF)

• Stimulation:

- Transcranial electrical stimulation (TES)
- Direct cortical and subcortical stimulation (DCS)
- Direct nerve stimulation (DNS)
- Transcutaneous intraoperative nerve stimulation (TINS)
- Direct muscle stimulation (DMS)
- Stimulation for visual evoked potentials (VEP)

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.

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510(k) Summary

ISIS Headboxes and ISIS Neurostimulator (ISIS Systems: ISIS Xpert^{plus}, ISIS Xpert, ISIS Xpress)

Date of preparation:	2026-09-24
510(k) Holder:	inomed Medizintechnik GmbH Im Hausgruen 29 79312 Emmendingen, Germany
Submitter and Application Correspondent:	Johannes Hoerth Regulatory Affairs Manager Phone: +49 7641 9414 836 Email: RA@inomed.com Hannah Barth Product Manager Active Devices Phone: +49 7641 94 14 546 Email: H.Barth@inomed.com
Manufacturing Site:	inomed Medizintechnik GmbH Im Hausgruen 29 79312 Emmendingen, Germany
Trade Name:	ISIS Headboxes and ISIS Neurostimulator (ISIS Systems: ISIS Xpert ^{plus} , ISIS Xpert, ISIS Xpress)
Regulation Medical Specialty:	Neurology
Classification Regulation:	21 CFR §882.1870 – Evoked response electrical stimulator
Product Code:	GWF (Class II) – Evoked Response Electrical Stimulator
Subsequent Product Codes:	GWE, GWJ, GWQ, ETN, IKN

**Substantially
Equivalent Devices:**
**Predicate device 510(k)
number**
**Predicate device
Manufacturer/Model**

K233292
(Primary Predicate
device)

inomed Medizintechnik GmbH /
ISIS Headboxes, ISIS
Neurostimulator, ISIS Xpert Plus,
ISIS Xpert, ISIS Xpress

K162199
(Secondary Predicate
device)

Cadwell Industries, Inc. /
Cascade IOMAX Intraoperative
Monitor

Device Description:

The ISIS Headboxes are equipped with referential or differential measurement technology or with a mixture of both. They amplify and digitize the incoming biosignals and transmit the results to a PC unit. The ISIS Neurostimulator is an evoked response stimulator and has 12 channels for high current stimulation as well as one channel for low-current direct nerve stimulation (DNS). The NeuroExplorer software, which forms an integral part of the ISIS Headboxes and ISIS Neurostimulator, is used as operating software for control and signal interpretation. The ISIS Headbox 5042XX and the ISIS Neurostimulator 504180 products need to be used in combination with corresponding accessories and other products in order to operate in accordance with their intended use. The functionality of the ISIS Headboxes and the ISIS Neurostimulator is assured only when used in combination with a PC unit and peripheral input devices, a system carrier, ISIS adaptor boxes (pods), and additional patient accessories for stimulation and recording. inomed Medizintechnik GmbH supplies the systems already pre-configured in the form of medical systems. These medical systems make up the ISIS System family and are named as follows: ISIS Xpertplus, ISIS Xpert, and ISIS Xpress. The patient accessories are out of scope of this 510(k).

**Intended Use of
Subject Device:**

ISIS Headboxes, ISIS
Neurostimulator, ISIS
Xpert Plus, ISIS Xpert,
ISIS Xpress

The product is used for intraoperative monitoring and testing during surgical procedures

- to examine neuronal tissue (central and peripheral nervous system) by recording and stimulation

The product can be used during surgical procedures that justify non-therapeutic clinical use of the following modalities or their combinations:

- Measurement:
 - Auditory evoked potentials (AEP)
 - Electroencephalography (EEG)
 - Electrocorticography (ECoG)
 - Electromyography (EMG)
 - Somatosensory evoked potentials (SSEP)
 - Motor evoked potentials (MEP)
 - Visual evoked potentials (VEP)
 - Train of Four (TOF)

**Intended Use of
Primary Predicate
Device:**

ISIS Headboxes, ISIS
Neurostimulator, ISIS
Xpert Plus, ISIS Xpert,
ISIS Xpress

- Stimulation:
 - Transcranial electrical stimulation (TES)
 - Direct cortical and subcortical stimulation (DCS)
 - Direct nerve stimulation (DNS)
 - Transcutaneous intraoperative nerve stimulation (TINS)
 - Direct muscle stimulation (DMS)
 - Stimulation for visual evoked potentials (VEP)

The product is used for intraoperative monitoring and testing during surgical procedures

- to examine neuronal tissue (central and peripheral nervous system) by recording and stimulation

The product can be used during surgical procedures that justify non-therapeutic clinical use of the following modalities or their combinations:

- Measurement:
 - Auditory evoked potentials (AEP)
 - Electroencephalography (EEG)
 - Electrocorticography (ECoG)
 - Electromyography (EMG)
 - Somatosensory evoked potentials (SSEP)
 - Motor evoked potentials (MEP)
 - Train of Four (TOF)
- Stimulation:
 - Transcranial electrical stimulation (TES)
 - Direct cortical and subcortical stimulation (DCS)
 - Direct nerve stimulation (DNS)
 - Transcutaneous intraoperative nerve stimulation (TINS)
 - Direct muscle stimulation (DMS)

**Intended Use of
Secondary Predicate
Device:**

Cascade IOMAX
Intraoperative Monitor

The Cascade IOMAX™ Intraoperative Monitor with Surgical Studio software (IOMAX) is an electroneurodiagnostic device that acquires, displays and stores physiologic data from peripheral sensory and motor nerves, muscles and the central nervous system, generated either spontaneously or elicited by well-defined stimuli. The acquired data are necessary to perform somatosensory, auditory and visual evoked potentials (EPs), electroencephalography (EEG), electromyography (EMG), transcranial motor evoked potentials (TcMEPs), direct cortical stimulation, nerve conduction studies and Train of Four (TOF) analysis. SpO2 measures and displays oxygen saturation and heart rate information.

The system also delivers direct nerve stimulation required for specific surgical procedures.

Evoked Potentials (EPs): IOMAX provides electrical, auditory or visual stimulation and measures, displays, records, and stores

the electrical activity of the nervous system in response to the stimulation.

EEG: IOMAX measures, displays, records, and stores electrical activity of the brain from two or more electrodes on the head.

Free Run EMG: IOMAX acquires, displays, records, and stores spontaneous EMG activity of motor nerves by continually displaying a live stream of mechanically induced myotome contractions.

TcMEP: IOMAX delivers transcranial stimulation via dedicated outputs for intraoperative assessment. Cortical Stimulation: IOMAX delivers Low Current Stimulation (LCS) during surgical procedures to map various areas of the cortex.

Triggered EMG (TEMG): IOMAX electrically stimulates the motor nerves, and displays, records, and stores the resulting compound muscle action potentials in the innervated muscle.

Nerve Conduction Study (NCS): IOMAX measures, displays, records, and stores sensory and motor nerve conduction time (latency) by applying a stimulus to peripheral nerves, the spinal cord, and the central nervous system.

Train of Four (TOF) or Twitch Test: IOMAX delivers a train of four pulses and measures, displays, records, and stores the compound muscle action potential amplitude fade for analysis.

SpO2: IOMAX measures and displays oxygen saturation and heart rate information.

Remote Reader: IOMAX provides passive, real time remote review of intraoperative monitoring for a physician outside of the operating room.

IOMAX is used by or under the direction of a licensed physician, surgeon, or neurologist in a professional healthcare facility environment for pre-operative, intraoperative and post-operative testing.

Conclusion of the intended use evaluation:

inomed Medizintechnik GmbH claims that the subject device and the predicate devices have the same intended use and indications for use. Both the predicate and subject devices can be used for the recording of electrophysiological signals and stimulating nerve and muscle tissues for intraoperative neuromonitoring.

Technology Comparison:

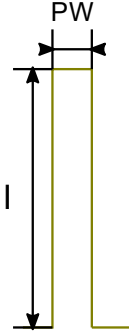
The technological characteristics of the ISIS Headboxes, ISIS Neurostimulator, ISIS Xpert Plus, ISIS Xpert, ISIS Xpress and the predicate devices are equivalent:

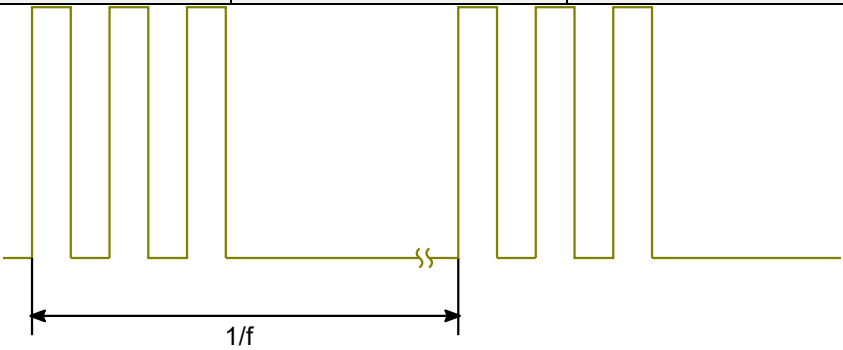
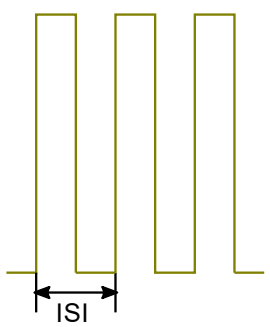
	Subject device	Primary predicate device	Secondary predicate device
Device	ISIS Headboxes, ISIS Neurostimulator, ISIS Xpert Plus, ISIS Xpert, ISIS Xpress	ISIS Headboxes, ISIS Neurostimulator, ISIS Xpert Plus, ISIS Xpert, ISIS Xpress	Cascade IOMAX Intraoperative Monitor
Software	NeuroExplorer 8.1	NeuroExplorer 8.0	Surgical Studio
Manufacturer	inomed Medizintechnik GmbH	inomed Medizintechnik GmbH	Cadwell Industries, Inc.
Clinical aspects			
Intended Use and Indications for use:	The product is used for intraoperative monitoring and testing during surgical procedures - to examine neuronal tissue (central and peripheral nervous system) by recording and stimulation The product can be used during surgical procedures that justify non-therapeutic clinical use of the following modalities or their combinations: - Measurement: - Auditory evoked potentials (AEP) - Electroencephalography (EEG) - Electrocorticography (ECoG) - Electromyography (EMG) - Somatosensory evoked potentials (SSEP) - Motor evoked potentials (MEP) - Visual evoked potentials (VEP) - Train of Four (TOF) - Stimulation: - Transcranial electrical stimulation (TES) - Direct cortical and subcortical stimulation (DCS) - Direct nerve stimulation (DNS) - Transcutaneous intraoperative nerve stimulation (TINS) - Direct muscle stimulation (DMS) - Stimulation for visual evoked potentials (VEP)	The product is used for intraoperative monitoring and testing during surgical procedures - to examine neuronal tissue (central and peripheral nervous system) by recording and stimulation The product can be used during surgical procedures that justify non-therapeutic clinical use of the following modalities or their combinations: - Measurement: - Auditory evoked potentials (AEP) - Electroencephalography (EEG) - Electrocorticography (ECoG) - Electromyography (EMG) - Somatosensory evoked potentials (SSEP) - Motor evoked potentials (MEP) - Train of Four (TOF) - Stimulation: - Transcranial electrical stimulation (TES) - Direct cortical and subcortical stimulation (DCS) - Direct nerve stimulation (DNS) - Transcutaneous intraoperative nerve stimulation (TINS) - Direct muscle stimulation (DMS)	The Cascade IOMAX™ Intraoperative Monitor with Surgical Studio software (IOMAX) is an electroneurodiagnostic device that acquires, displays and stores physiologic data from peripheral sensory and motor nerves, muscles and the central nervous system, generated either spontaneously or elicited by well-defined stimuli. The acquired data are necessary to perform somatosensory, auditory and visual evoked potentials (EPs), electroencephalography (EEG), electromyography (EMG), transcranial motor evoked potentials (TcMEPs), direct cortical stimulation, nerve conduction studies and Train of Four (TOF) analysis. SpO2 measures and displays oxygen saturation and heart rate information. The system also delivers direct nerve stimulation required for specific surgical procedures. Evoked Potentials (EPs): IOMAX provides electrical, auditory or visual stimulation and measures, displays, records, and stores the electrical activity of the nervous system in response to the stimulation. EEG: IOMAX measures, displays, records, and stores electrical activity of the brain from two or more electrodes on the head. Free Run EMG: IOMAX acquires, displays, records, and stores spontaneous EMG activity of motor nerves by continually displaying a live stream of mechanically induced myotome contractions. TcMEP: IOMAX delivers transcranial stimulation via dedicated outputs for intraoperative assessment. Cortical Stimulation: IOMAX delivers Low Current Stimulation (LCS) during

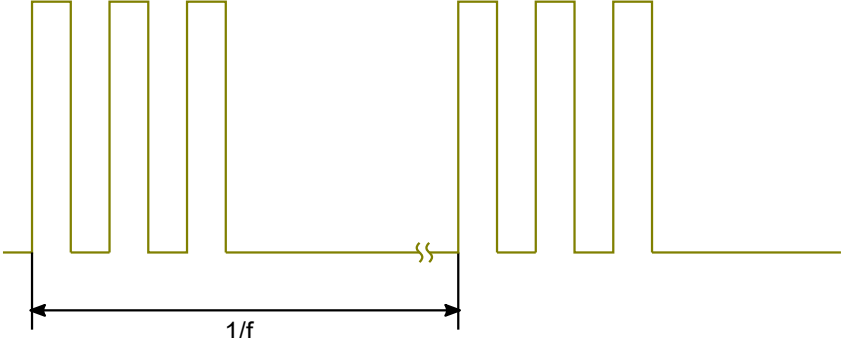
	Subject device	Primary predicate device	Secondary predicate device
			surgical procedures to map various areas of the cortex. Triggered EMG (TEMG): IOMAX electrically stimulates the motor nerves, and displays, records, and stores the resulting compound muscle action potentials in the innervated muscle. Nerve Conduction Study (NCS): IOMAX measures, displays, records, and stores sensory and motor nerve conduction time (latency) by applying a stimulus to peripheral nerves, the spinal cord, and the central nervous system. Train of Four (TOF) or Twitch Test: IOMAX delivers a train of four pulses and measures, displays, records, and stores the compound muscle action potential amplitude fade for analysis. SpO2: IOMAX measures and displays oxygen saturation and heart rate information. Remote Reader: IOMAX provides passive, real time remote review of intraoperative monitoring for a physician outside of the operating room. IOMAX is used by or under the direction of a licensed physician, surgeon, or neurologist in a professional healthcare facility environment for pre-operative, intraoperative and post-operative testing.
Biological aspects			
Tissue contact	"The ISIS Headboxes and ISIS Neurostimulator including accessories as part of ISIS systems (ISIS Xpertplus, ISIS Xpert, ISIS Xpress) have no patient contact materials (...)"	"The ISIS Headboxes and ISIS Neurostimulator including accessories as part of ISIS IOM Systems (ISIS Xpertplus, ISIS Xpert, ISIS Xpress) have no patient contact materials (...)"	"The IOMAX has no patient contact materials, and therefore this section does not apply to them. The SpO2 sensor and accessories for use with the IOMAX have patient contact materials and are made from medical grade biocompatible materials. (...)"
Technical aspects			
Electrical safety	Complete basic safety testing accredited by CSA Group attesting to the conformity with following standards: IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020	Complete basic safety testing accredited by CSA Group attesting to the conformity with following standards: IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)	Cascade IOMAX fulfills the following internationally recognized safety standards for electrical medical devices: ANSI/AAMI ES60601-1: 2005/(R)2012, C1:2009/(R)2012, A2:2010/(R)2012

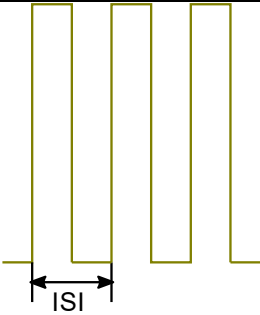
	Subject device	Primary predicate device	Secondary predicate device
Electro-magnetic compatibility	Electromagnetic compatibility tests according to the standards: IEC 60601-1-2 Ed4.1 (2020)	Electromagnetic compatibility tests according to the standards: IEC 60601-1-2, Ed. 4.0, 2014	Electromagnetic compatibility tests according to the standards: IEC 60601-1-2, Ed. 4.0, 2014
Performance testing standards	Performance testing according to the standards:	Performance testing according to the standards:	Performance testing according to the standards:
	IEC 60601-1-6:2010, AMD1:2013, AMD2:2020 for use in conjunction with IEC 62366-1:2015, AMD1:2020, and IEC 60601-1:2005, AMD1:2012, AMD2:2020	IEC 60601-1-6:2010, AMD1:2013 for use in conjunction with IEC 62366:2007, AMD1:2014 and IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1: 2012 or equivalent consolidated version IEC 60601-1:2012 (Edition 3.1)	IEC 60601-1-6:2010
	IEC 60601-2-40:2016 for use in conjunction with IEC 60601-1:2005, CORR1:2006, CORR2:2007, AMD1:2012	IEC 60601-2-40:2016 for use in conjunction with IEC 60601-1:2005, CORR1:2006, CORR2:2007, AMD1:2012	IEC 60601-2-40:1998
	IEC 62304:2006+AMD1:2015	IEC 62304:2006+AMD1:2015	IEC 62304:2006
	IEC 62366-1:2015	IEC 62366-1:2015	IEC 62366:2007
	IEC 80601-2-26:2019	IEC 80601-2-26:2019	IEC 60601-2-26:2012
Essential performance	Electrical, acoustic and visual stimulation The product applies electrical and visual stimulation pulses within application-related specifications. The pulse amplitude, the pulse width and the stimulation frequency of the ISIS System stimulation signal meet the adjusted value with a tolerance of $\pm 30\%$ (IEC 60601-2-40:2016, Section 201.12.1).	Electrical and acoustic stimulation The product applies electrical stimulation pulses within application-related specifications. The pulse amplitude, the pulse width and the stimulation frequency of the ISIS System stimulation signal meet the adjusted value with a tolerance of $\pm 30\%$ (IEC 60601-2-40:2016, Section 201.12.1).	Cadwell checks for essential performance when the user's system is sent in for preventive maintenance. 1. The IOMAX system must deliver electrical stimulation as described in IEC 60601-2-40 without unintended stimulation.
	Signal acquisition The product provides the biosignal feedback within defined latency of $\leq 3s$.	Signal acquisition The product provides the biosignal feedback within defined latency of $\leq 3s$.	-
	The product meets all essential performance requirements as specified in IEC 80601-2-26:2019:	The product meets all essential performance requirements as specified in IEC 80601-2-26:2019:	2. The IOMAX 16-channel amplifier must meet all essential performance requirements as specified in IEC 60601-2-26:2012:
	201.12.1.102 Accuracy of amplitude and rate of variation	201.12.1.102 Accuracy of amplitude and rate of variation	201.12.1.101.1 Signal reproduction accuracy
	201.12.1.103 Input dynamic range and differential offset voltage	201.12.1.103 Input dynamic range and differential offset voltage	201.12.1.101.2 Input dynamic range and differential offset voltage
	201.12.1.104 Input noise	201.12.1.104 Input noise	201.12.1.101.3 Input noise
	201.12.1.105 Frequency response	201.12.1.105 Frequency response	201.12.1.101.4 Frequency response
	201.12.1.106 Common mode rejection	201.12.1.106 Common mode rejection	201.12.1.101.5 Common mode rejection
Protection against electrical shock	Class I protection	Class I protection	Class I protection

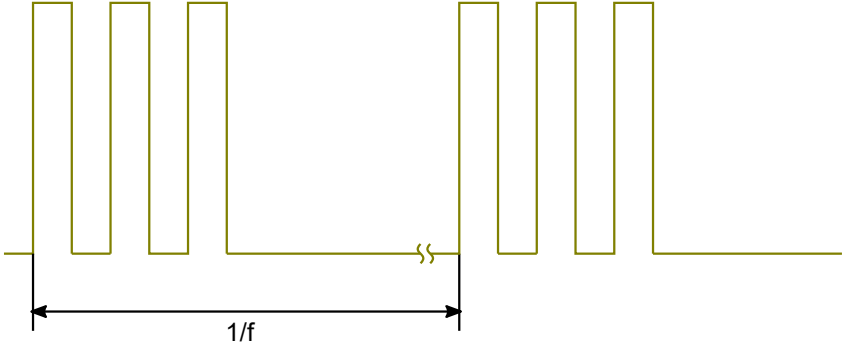
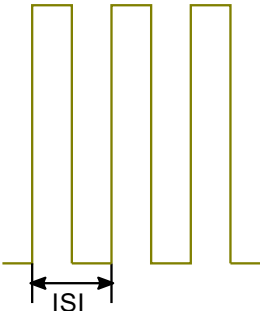
	Subject device	Primary predicate device	Secondary predicate device	
Protection against electrical shock of patient leads	Device type BF (Body Floating)	Device type BF (Body Floating)	Device type BF (Body Floating)	
Risk management	Risk Management according to standard: DIN EN ISO 14971:2022-04	Risk Management according to standard: ISO 14971: 2019	Risk Management according to standard: ISO 14971: 2007	
System configuration	Computer-based equipment with dedicated hardware and software components	Computer-based equipment with dedicated hardware and software components	Computer-based equipment with dedicated hardware and software components	
Signal recording				
Measurement principle	Amplifiers based on differential (bipolar) and referential (unipolar) type of recording	Amplifiers based on differential (bipolar) and referential (unipolar) type of recording	Amplifiers based on differential (bipolar) and referential (unipolar) type of recording	
Amplifier components	Desired combination of ISIS Headboxes with a total of 64 channels	Desired combination of ISIS Headboxes with a total of 64 channels	One (1) Cortical Module Up to four (4) Limb Modules	
Number of amplifier channels	Up to 64:		Up to 48:	
	Module	Channels	Module	Channels
	ISIS Headbox 16 Ch. REF (504261)	Unipolar: 16 Bipolar: 0	ISIS Headbox 16 Ch. REF (504261)	Unipolar: 16 Bipolar: 0
	ISIS Headbox 16 Ch. DIF (504271)	Unipolar: 0 Bipolar: 16	ISIS Headbox 16 Ch. DIF (504271)	Unipolar: 0 Bipolar: 16
	ISIS Headbox 16 Ch. REF – AEP (504281)	Unipolar: 16 Bipolar: 0	ISIS Headbox 16 Ch. REF – AEP (504281)	Unipolar: 16 Bipolar: 0
	ISIS Headbox 8 Ch. DIF – 8 Ch. REF – AEP (504285)	Unipolar: 8 Bipolar: 8	ISIS Headbox 8 Ch. DIF – 8 Ch. REF – AEP (504285)	Unipolar: 8 Bipolar: 8
Measurement range	Conformant with IEC 80601-2-26:2019, clause 201.12.1.103 Input dynamic range and differential offset voltage.	Conformant with IEC 80601-2-26:2019, clause 201.12.1.103 Input dynamic range and differential offset voltage.	Conformant with IEC 60601-2-26:2012, clause 201.12.1.101.2 Input dynamic range and differential offset voltage	
A/D resolution	16-bit	16-bit	16-bit	
Hardware bandpass	Hardware high-pass filter: 0.5-120 Hz on all modules	Hardware high-pass filter: 0.5-120 Hz on all modules	Hardware high-pass filter: 0.3-100 Hz on Cortical Module 0.5-100 Hz on Limb Module	
	Hardware low-pass filter: 2500, 5000 Hz on all modules	Hardware low-pass filter: 2500, 5000 Hz on all modules	Hardware low-pass filter: 30-5000 Hz on Cortical Module 30-10000 Hz on Limb Module	
Sampling frequency	20 kHz	20 kHz	25 kHz	
Notch filter	50, 60 Hz	50, 60 Hz	50, 60 Hz	
Common-mode rejection ratio (CMRR)	> 100 dB	> 100 dB	> 115 dB	
	Conformant with IEC 80601-2-26:2019, clause 201.12.1.106 Common mode rejection.	Conformant with IEC 80601-2-26:2019, clause 201.12.1.106 Common mode rejection.	Conformant with IEC 60601-2-26:2012, clause 201.12.1.101.5 Common mode rejection	

	Subject device	Primary predicate device	Secondary predicate device
Amplifier noise	Conformant with IEC 80601-2-26:2019, clause 201.12.1.104 Input noise	Conformant with IEC 80601-2-26:2019, clause 201.12.1.104 Input noise	Conformant with IEC 60601-2-26:2012, clause 201.12.1.101.3 Input noise
Stimulation			
Stimulation components	Max. one (1) ISIS Neurostimulator including: High: High Current (HC) Stimulator with max. twelve (12) outputs Low: Direct Nerve Stimulator (DNS) with one (1) output	Max. one (1) ISIS Neurostimulator including: High: High Current (HC) Stimulator with max. twelve (12) outputs Low: Direct Nerve Stimulator (DNS) with one (1) output	High: Up to four (4) Limb Modules Low: One (1) Cortical Module
Normative conformity	Conformant to IEC 60601-2-40:2016	Conformant to IEC 60601-2-40:2016	Conformant to IEC 60601-2-40:1998
TcMEP stimulation	Realized by High Current Stimulator (HC) in transcranial stimulation mode	Realized by High Current Stimulator (HC) in transcranial stimulation mode	Realized by Cortical Module in TcMEP mode
Stimulator type	Current controlled	Current controlled	Current controlled and optional voltage controlled
No. of outputs	12	12	9
Stimulation intensity (I) and pulse width (PW)			
	Current controlled: up to 250 mA (voltage limit of 410 V) Voltage controlled: n/a 0.05 – 2 ms	Current controlled: up to 250 mA (voltage limit of 410 V) Voltage controlled: n/a 0.05 – 2 ms	Current controlled: up to 1500 mA (voltage limit of 1000 V) Voltage controlled: up to 1000 V 0.05 – 0.5 ms
Intensity step	Constant current: 0.1 mA Constant voltage: n/a	Constant current: 0.1 mA Constant voltage: n/a	Constant current: 10 mA Constant voltage: 5 V
No. of stimulus pulses	1-9	1-9	1-9

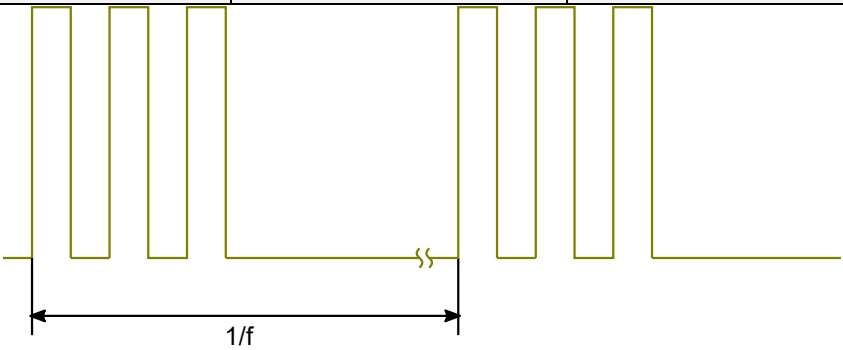
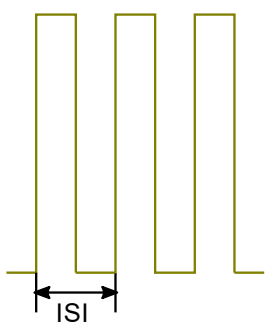
	Subject device	Primary predicate device	Secondary predicate device
Stimulation frequency (f) range			
	Up to 500 Hz	Up to 500 Hz	Up to 1 Hz
Limitation of stimulation frequency (f)	1/10 pulse width to stimulation period ratio	1/10 pulse width to stimulation period ratio	None
Limitation of inter-stimulus interval (ISI)			
	Limited to ½ pulse width to ISI	Limited to ½ pulse width to ISI	Minimum ISI: 0.1 ms
Absolute minimum inter-stimulus interval (ISI)	0.1 ms	0.1 ms	0.1 ms
Maximum charge per phase	189.66 µC	189.66 µC	50 µC
Maximum RMS stimulation intensity @ 1 kΩ	30 mA RMS	30 mA RMS	7.1 mA RMS
Minimum electrode size	n/a	n/a	Low EP: 0.04 cm ² TcMEP: 0.5 cm ²
Maximum current density	90.8 mA/cm ²	90.8 mA/cm ²	Low EP: 90.8 mA/cm ² TcMEP: 14.1 mA/cm ²
Maximum charge density	61.5 µC/cm ²	61.5 µC/cm ²	Low EP: 275 µC/cm ² TcMEP: 100 µC/cm ²
Maximum power density @ 1 kΩ	160 W/cm ²	160 W/cm ²	Low EP: 10 W/cm ² TcMEP: 2,000 W/cm ²

	Subject device	Primary predicate device	Secondary predicate device
Power limitation	<50 mJ/pulse Conformant to IEC 60601-2-40:2016, clause 201.12.4.103.	<50 mJ/pulse Conformant to IEC 60601-2-40:2016, clause 201.12.4.103.	<50 mJ/pulse IEC 60601-2-40:1998 (1st ed.), clause 201.12.4.103.
High-current stimulator for SEP and TOF	Realized by High Current Stimulator (HC) in subcutaneous stimulation (SEP, TOF) mode	Realized by High Current Stimulator (HC) in subcutaneous stimulation (SEP, TOF) mode	Realized by Limb Module in High EP mode
Stimulator type	Constant current	Constant current	Constant current
No. of outputs	12	12	5
Stimulation intensity (I)			
	Accessory-dependent	Accessory-dependent	Up to 100 mA
Intensity step	0.1 mA	0.1 mA	0.5 mA
Pulse width (PW)	0.05 – 2 ms	0.05 – 2 ms	0.05 – 1 ms
No. of stimulus pulses	1-9	1-9	1
Stimulation frequency (f) range			
	SEP: Up to 500 Hz TOF: 2 Hz (fixed)	SEP: Up to 500 Hz TOF: 2 Hz (fixed)	Up to 50 Hz
Limitation of stimulation frequency (f)	1/10 pulse width to stimulation period ratio	1/10 pulse width to stimulation period ratio	None

	Subject device	Primary predicate device	Secondary predicate device
Limitation of inter-stimulus interval (ISI)			
	Limited to ½ pulse width to ISI	Limited to ½ pulse width to ISI	n/a (only 1 pulse possible)
Absolute minimum inter-stimulus interval (ISI)	0.1 ms	0.1 ms	n/a (only 1 pulse possible)
Maximum charge per phase	150 µC	150 µC	30 µC
Maximum RMS stimulation intensity	Accessory-dependent	Accessory-dependent	Low EP: 3.6 mA High EP: 3.2 mA
Minimum electrode size	n/a	n/a	Low EP: 0.04 cm ² High EP: 0.5 cm ²
Maximum current density	90.8 mA/cm ²	90.8 mA/cm ²	Low EP: 90.8 mA/cm ² High EP: 6.4 mA/cm ²
Maximum charge density	150.0 µC/cm ²	150.0 µC/cm ²	Low EP: 275 µC/cm ² High EP: -
Maximum power density	20.7 W/cm ²	20.7 W/cm ²	Low EP: 10 W/cm ² High EP: -
Power limitation	<50 mJ/pulse Conformant to IEC 60601-2-40:2016, clause 201.12.4.103.	<50 mJ/pulse Conformant to IEC 60601-2-40:2016, clause 201.12.4.103.	<50 mJ/pulse IEC 60601-2-40:1998, clause 201.12.4.103.
Low-current stimulator for direct cortical stimulation:	Realized by High Current Stimulator (HC) in direct cortical stimulation mode	Realized by High Current Stimulator (HC) in direct cortical stimulation mode	Realized by Cortical Module in Low EP mode
Stimulator type	Constant current	Constant current	Constant current

	Subject device	Primary predicate device	Secondary predicate device
Stimulation intensity (I)			
	Accessory-dependent	Accessory-dependent	Up to 20 mA
Intensity step	0.01 mA	0.01 mA	0.01 mA
Pulse width (PW)	0.05 – 2 ms	0.05 – 2 ms	0.05 – 1 ms
No. of stimulus pulses	1 – 9	1 – 9	1
Stimulation frequency (f) range			
	Up to 500 Hz	Up to 500 Hz	Up to 50 Hz
Limitation of stimulation frequency (f)	1/10 pulse width to stimulation period ratio	1/10 pulse width to stimulation period ratio	None
Limitation of inter-stimulus interval (ISI)			
	Limited to ½ pulse width to ISI	Limited to ½ pulse width to ISI	n/a (only 1 pulse possible)
Absolute minimum inter-stimulus interval (ISI)	0.1 ms	0.1 ms	n/a (only 1 pulse possible)

	Subject device	Primary predicate device	Secondary predicate device
Maximum charge per pulse	60 μC	60 μC	20 μC
Maximum RMS stimulation intensity	Accessory-dependent	Accessory-dependent	3.6 mA RMS
Minimum electrode size	n/a	n/a	Low EP: 0.04 cm^2
Maximum current density	90.8 mA/cm^2	90.8 mA/cm^2	Low EP: 90.8 mA/cm^2
Maximum charge density	150.8 $\mu\text{C}/\text{cm}^2$	150.8 $\mu\text{C}/\text{cm}^2$	Low EP: 275 $\mu\text{C}/\text{cm}^2$
Maximum power density	7.1 W/cm^2	7.1 W/cm^2	Low EP: 10 W/cm^2
Power limitation	≤ 50 mJ/pulse Conformant to IEC 60601-2-40:2016, clause 201.12.4.103.	≤ 50 mJ/pulse Conformant to IEC 60601-2-40:2016, clause 201.12.4.103.	< 50 mJ/pulse IEC 60601-2-40:1998, clause 201.12.4.103.
Low-current stimulator for direct nerve stimulation:	Realized by Direct Nerve Stimulator (DNS) in direct nerve stimulation mode	Realized by Direct Nerve Stimulator (DNS) in direct nerve stimulation mode	Realized by Cortical Module in Low EP mode
Stimulator type	Constant current	Constant current	Constant current
No. of outputs	1	1	1 + 1 (optional)
Stimulation intensity (I)			
	Accessory-dependent	Accessory-dependent	Up to 20 mA
Intensity step	0.01 mA	0.01 mA	0.01 mA
Pulse width (PW)	0.05 – 2 ms	0.05 – 2 ms	0.05 – 1 ms
No. of stimulus pulses	1 – 9	1 – 9	1

	Subject device	Primary predicate device	Secondary predicate device
Stimulation frequency (f) range			
	Up to 500 Hz	Up to 500 Hz	Up to 50 Hz
Limitation of stimulation frequency (f)	1/10 pulse width to stimulation period ratio	1/10 pulse width to stimulation period ratio	None
Limitation of inter-stimulus interval (ISI)			
	Limited to ½ pulse width to ISI	Limited to ½ pulse width to ISI	n/a (only 1 pulse possible)
Absolute minimum inter-stimulus interval (ISI)	0.1 ms	0.1 ms	n/a (only 1 pulse possible)
Maximum charge per pulse	10 µC	10 µC	20 µC
Maximum RMS stimulation intensity	Accessory-dependent	Accessory-dependent	3.6 mA RMS
Minimum electrode size	n/a	n/a	Low EP: 0.04 cm ²
Maximum current density	90.8 mA/cm ²	90.8 mA/cm ²	Low EP: 90.8 mA/cm ²
Maximum charge density	158 µC/cm ²	158 µC/cm ²	Low EP: 275 µC/cm ²
Maximum power density	1.25 W/cm ²	1.25 W/cm ²	Low EP: 10 W/cm ²
Power limitation	<50 mJ/pulse	<50 mJ/pulse	<50 mJ/pulse

	Subject device	Primary predicate device	Secondary predicate device
	Conformant to IEC 60601-2-40:2016, clause 201.12.4.103.	Conformant to IEC 60601-2-40:2016, clause 201.12.4.103.	IEC 60601-2-40:1998 (1st ed.), clause 201.12.4.103.
Other			
Operating principle	The device is an active medical product controlled using operating software. The product provides visual feedback using a separate display. The product provides auditory feedback using the PC loudspeakers. The user interacts with the system using a keyboard and mouse. The software controls are displayed on the screen and are accessible using the mouse and software. Additionally, the system offers redundant mouse functionality by providing a touch interface.	The device is an active medical product controlled using operating software. The product provides visual feedback using a separate display. The product provides auditory feedback using the PC loudspeakers. The user interacts with the system using a keyboard and mouse. The software controls are displayed on the screen and are accessible using the mouse and software. Additionally, the system offers redundant mouse functionality by providing a touch interface.	The device is an active medical product controlled using operating software The product provides visual feedback using a separate display. The product provides auditory feedback using the PC loudspeakers. The user interacts with the system using a keyboard and mouse. The software controls are displayed on the screen and are accessible using the mouse and software.
Accessories/ components	540559 Grid-TES-Stimulation Matrix (for 8-channel electrodes)	540559 Grid-TES-Stimulation Matrix (for 8-channel electrodes)	LCSwap
	540560 Grid-TES-Stimulation Matrix (for 16-channel electrodes)	540560 Grid-TES-Stimulation Matrix (for 16-channel electrodes)	
	540501 SEP Stimulation Adaptor for ISIS Neurostimulator	540501 SEP Stimulation Adaptor for ISIS Neurostimulator	TCS-9 Output Extender
	540510 MEP Stimulation Adaptor for Grid/TES Stimulation matrix	540510 MEP Stimulation Adaptor for Grid/TES Stimulation matrix	
	540511 MEP Stimulation Adaptor for ISIS Neurostimulator	540511 MEP Stimulation Adaptor for ISIS Neurostimulator	
	540522 EP Adaptor for ISIS Headbox 16 Ch. REF – AEP	540522 EP Adaptor for ISIS Headbox 16 Ch. REF – AEP	16 Channel Input Extender
	540523 EP Adaptor for ISIS Headbox 8 Ch. DIF – 8 Ch. REF – AEP	540523 EP Adaptor for ISIS Headbox 8 Ch. DIF – 8 Ch. REF – AEP	
	540524 EP Adaptor for ISIS Headbox 16 Ch. REF	540524 EP Adaptor for ISIS Headbox 16 Ch. REF	
	540525 EP Adaptor for 504285 EP Adaptor for ISIS Headbox 8Ch.DIF-8Ch.REF-AEP	540525 EP Adaptor for 504285 EP Adaptor for ISIS Headbox 8Ch.DIF-8Ch.REF-AEP	
	540531 EMG/MEP-Adaptor Ch. 1-8 for 504271 for ISIS Headbox 16 Ch. DIF	540531 EMG/MEP-Adaptor Ch. 1-8 for 504271 for ISIS Headbox 16 Ch. DIF	
	540532 EMG/MEP-Adaptor Ch. 9-16 for 504271 for ISIS Headbox 16 Ch. DIF	540532 EMG/MEP-Adaptor Ch. 9-16 for 504271 for ISIS Headbox 16 Ch. DIF	

	Subject device	Primary predicate device	Secondary predicate device
	540533 EMG/MEP-Adaptor Ch. 1-8 for 504271	540533 EMG/MEP-Adaptor Ch. 1-8 for 504271	
	SightSaver Visual Stimulator	-	LED Goggles with disposable foam for visual stimulation
	540340 AEP Insert Earphones	540340 AEP Insert Earphones	Insert Earphones for auditory stimulation

Optional accessory: SightSaver Visual Stimulator

The SightSaverMini™ Visual Stimulator was previously cleared under K113785 and may be used as an optional accessory for VEP testing. Stimulation characteristics include:

- Intensity: 5.875 lm to 7.65 lm (This parameter reflects the inherent light output variation of the SightSaver Visual Stimulator at 20mA input current provided by the ISIS Neurostimulator.)
- Pulse width: 5 ms
- Frequency: 0.5 Hz to 1 Hz
- Pulse form: Flash
- Pulse types: Left, right, both sides

Summary of

Performance Testing:

Biocompatibility:

The ISIS Headboxes and ISIS Neurostimulator (ISIS Systems: ISIS Xpert Plus, ISIS Xpert, ISIS Xpress) have no patient contact materials, and therefore this section does not apply.

Software:

The Documentation Level of the inomed NeuroExplorer Software is ENHANCED DOCUMENTATION. The software was designed and developed according to a rigorous development process, including software verification and validation. Software information is provided in accordance with internal requirements and the following guidance documents and standards:

- FDA Guidance: Content of Premarket Submissions for Device Software Functions, June 14, 2023
- FDA Guidance: Off-The-Shelf Software Use in Medical Devices, August 11, 2023
- FDA Guidance: General Principles of Software Validation; Final Guidance for Industry and FDA Staff, January 11, 2002
- FDA Guidance: Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions, February 2026
- FDA Guidance: Cybersecurity in Medical Devices: Refuse to Accept Policy for Cyber Devices and Related Systems Under Section 524B of the FD&C Act, March 30, 2023
- IEC 62304:2006+A1:2015, Medical device software - Software life cycle processes

Electrical, Mechanical and Thermal Testing:	Test results indicate that the inomed NeuroExplorer Software complies with its predetermined specifications and the applicable guidance documents and standards. The ISIS Headboxes and ISIS Neurostimulator including accessories as part of ISIS Systems (ISIS Xpert Plus, ISIS Xpert, ISIS Xpress) were tested according to the following standards: • IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. • IEC 80601-2-26:2019, Medical electrical equipments – Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs • IEC 60601-2-40:2016, Medical electrical equipments – Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment Test results demonstrate that the products comply with the applicable standards.
Electromagnetic Compatibility Testing:	The ISIS Headboxes and ISIS Neurostimulator including accessories as part of ISIS Systems (ISIS Xpert Plus, ISIS Xpert, ISIS Xpress) were tested according to the following standards: • IEC 60601-1-2:2014 + AMD1: 2020, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests. Test results demonstrate that the products comply with the applicable standards.
Performance Testing – Bench:	The ISIS Headboxes and ISIS Neurostimulator (ISIS Systems: ISIS Xpert Plus, ISIS Xpert, ISIS Xpress) were evaluated in accordance with internal verification and validation requirements as part of the design control process. The results of these activities demonstrate that the device continues to meet its predetermined specifications and intended performance characteristics.
Performance Testing – Clinical:	No additional clinical testing was performed for the ISIS Headboxes and ISIS Neurostimulator (ISIS Systems: ISIS Xpert Plus, ISIS Xpert, ISIS Xpress). Therefore, this section does not apply.
Conclusion:	Verification and validation activities were undertaken in order to establish the performance and safety characteristics of the ISIS Headboxes and ISIS Neurostimulator (ISIS Systems: ISIS Xpert Plus, ISIS Xpert, ISIS Xpress), including NeuroExplorer 8 software and associated accessories. The results of these

activities demonstrate that the devices perform as intended and are at least as safe and effective as the predicate devices.

Therefore, the ISIS Headboxes and ISIS Neurostimulator (ISIS Systems: ISIS Xpert Plus, ISIS Xpert, ISIS Xpress) are considered substantially equivalent to the predicate devices.