August 13, 2026

Covidien LP
Monica Gupta
Senior Regulatory Affairs Specialist
15 Hampshire St.
Mansfield, MA 02048

Re: K260907
Trade/Device Name: BIS™ Advance pEEG Module
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLW
Dated: July 7, 2026
Received: July 7, 2026

Dear Monica Gupta:

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 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,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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.

510(k) Number *(if known)*
K260907

Device Name
BIS™ Advance pEEG Module

Indications for Use *(Describe)*
The BIS™ Advance pEEG Module when connected to the Host Monitor is intended for monitoring the state of the brain by data acquisition of EEG signals under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. The BIS™ Advance pEEG Module and all its associated parameters, is intended for use on adult and pediatric patients (4 years old and above) within a hospital or medical facility.

For adult patients, the BIS™ Index, one of the BIS™ Advance pEEG Module's output parameters, may be used to guide anesthetic administration of desflurane, isoflurane, propofol and sevoflurane with balanced anesthetic techniques in order to monitor the anesthetic effects on the brain.

The use of the BIS™ Index for monitoring may be associated with the following when used with propofol anesthesia: reduction in primary anesthetic use; reduction in emergence and recovery time; and reduction in incidence of awareness with recall.

For pediatric patients, ages 4 and above, the BIS™ Index, one of the BIS™ Advance pEEG Module's output parameters, may be used to guide anesthetic administration of sevoflurane with balanced anesthetic techniques in order to monitor the anesthetic effects on the brain.

The use of the BIS™ Index in pediatric patients, when used with sevoflurane anesthesia, has demonstrated a reduction in primary anesthetic use.

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) SUMMARY

K260907

This summary of 510(k) safety and effectiveness information for the BIS™ Advance pEEG Module is submitted in accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with the requirements of 21 CFR 807.92.

I. SUBMITTER INFORMATION

Submitted By:	Covidien llc[1] 200 Medtronic Dr Lafayette, CO 80026
Contact Person:	Monica Gupta, Senior Regulatory Affairs Specialist Phone: 651-338-8794 Email: monica.gupta@medtronic.com
Secondary Contact:	Jessica Swafford, Senior Regulatory Affairs Manager Phone: 720-697-0165 Email: jessica.swafford@medtronic.com
Date:	August 11, 2026

II. DEVICE

Trade or Proprietary Name:	BIS™ Advance pEEG Module
Common Name:	BIS™ Advance pEEG Module
Regulation Number:	21 CFR § 882.1400
Classification Name:	Electroencephalograph
Regulatory Class:	Class II
Product Code:	OLW, OMC, OLT, ORT
Review Panel:	Anesthesiology/Neurology

[1] Covidien llc is a wholly owned subsidiary of Medtronic Inc.

III. PREDICATE & REFERENCE DEVICES

Predicate Device:

Predicate Manufacturer: Covidien LLC (acquired by Medtronic)
Predicate Device Name: BISX™/BISX4™ Module cleared as part of BIS™ Advance Monitoring System
Predicate 510(k): K230693

IV. DEVICE DESCRIPTION

The BIS™ Advance pEEG Module is a finished medical device that, when connected to a compatible host monitor, such as the BIS™ Advance Monitor (cleared as part of BIS™ Advance Monitoring System under K230693), and paired with the BIS™ Sensors (cleared under K143506), monitors the hypnotic state of the brain by acquisition and processing of EEG signals.

- The BIS™ Advance pEEG Module processes raw EEG data to produce a single number, called the Bi-spectral Index (BIS™ index), a single numerical value correlating with the patient's level of hypnosis (depth of anesthesia), and transmits it to the Host Monitor for display on the monitor screen.
- Together with calculating the BIS™ index value, the BIS™ Advance pEEG Module also derives other processed EEG parameters using the raw EEG data to support clinical decisions and sends them to the Host Monitor that may display them on screen.

The BIS™ Advance pEEG Module connects to the monitor using a Host Cable on one side and to a BIS™ Sensor using a Sensor Cable on the other side, see **Figure 1**. It is capable of processing up to four (4) EEG channels, depending on the type of connected sensor. For 2-channel sensors, the system produces one BIS™ index value; for 4-channel sensors, the system produces a total of 2 BIS™ index values, one for each brain hemisphere. The module includes a Sensor Cable, which has an internal unit called the Front-End (digital signal converter), which contains software and hardware, and uses them to digitize the EEG signals, detect sensor-related errors and malfunctions, and communicate with the Back-End. The Back-End contains an internal component called the pEEG Module, which houses the “Main Board” and software to process the digitized EEG, produce the processed parameters using the BIS™ algorithm, and communicate with both the Host and the Front-End.

Both the Front-End and Back-End are equipped with software and hardware components that store encryption keys and perform authentication, encryption, and decryption as necessary.

The BIS™ Advance pEEG Module is available in several configurations, differentiated by the type of Monitor Connector integrated part of the Host Cable (identified as component "**A**" in **Figure 1**) to ensure compatibility with a variety of patient monitors. One configuration is designed for use with the Medtronic

BIS™ Advance Monitor, while the other configurations maintain backward compatibility with host monitors from other legal manufacturers. Each configuration is provided with an eIFU insert directing users to download the Instructions for Use from the Medtronic website.

Similar to its predicate, the BIS™ Advance pEEG Module is a non-sterile, reusable device. The BIS™ Advance pEEG Module maintains the same intended use, core functionality, and BIS™ algorithm as the predicate BISX™/BISX4™ Module (cleared as part of BIS™ Advance Monitoring System under K230693) while incorporating updated hardware, software enhancements, and improved ECG artifact filtering. The BIS™ Advance pEEG Module is powered by the host monitor via the host cable and does not generate alarms. It stores non-PHI operational data that may be retrieved using the BIS™ Advance Connect Application, a non-medical software tool used outside active monitoring.

The subject device is compatible with the 510(k) cleared BIS™ Sensors (K143506) and is available in multiple configurations with different monitor connectors to support both Medtronic and host monitors from other legal manufacturers. Both the Back-End and Front-End components support authentication and encrypted communication. The BIS™ Advance pEEG Module is intended for use by trained healthcare professionals within hospital environments.

Table 1: BIS™ Advance pEEG Module Components

Identifier	Component
A	Monitor Connector (part of the Host Cable and Back End)
B	pEEG Module Host Cable (Part of Back End)
C	pEEG Module (Part of Back End)
D	Sensor Cable Module Connector
E	pEEG Module Sensor Cable (also called Front-End Cable)
F	Cable Management Solution
G	Sensor Cable Clip
H	Sensor Cable Connector (also called Front-End)
I	Mount (Also called Cradle)

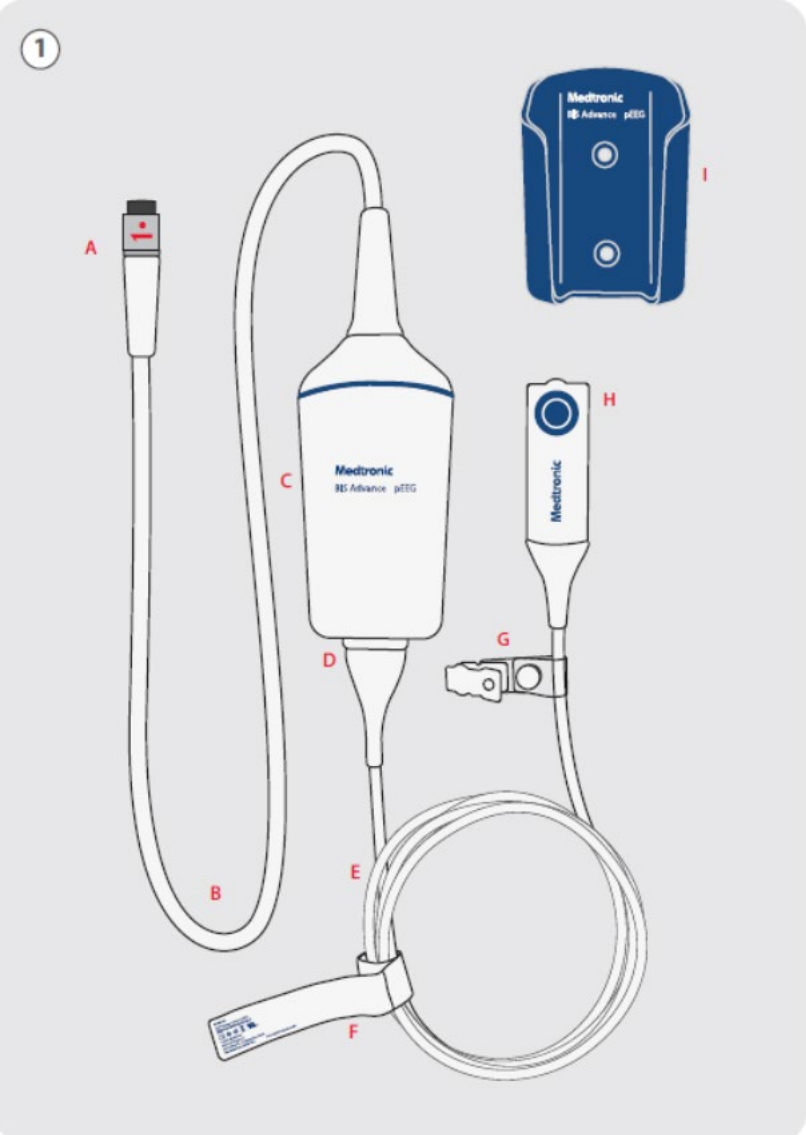

Figure 1: BIS™ Advance pEEG Module Components

V. INDICATIONS FOR USE

The BIS™ Advance pEEG Module when connected to a Host Monitor, is intended for monitoring the state of the brain by data acquisition of EEG signals under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. The BIS™ Advance pEEG Module, and all its associated parameters, is intended for use on adults and pediatric patients (4 years old and above) within a hospital or medical facility.

For adult patients, the BIS™ Index, one of the BIS™ Advance Monitoring System's output parameters, may be used to guide anesthetic administration of desflurane, isoflurane, propofol and sevoflurane with balanced anesthetic techniques in order to monitor the anesthetic effects on the brain.

The use of the BIS™ Index for monitoring may be associated with the following when used with propofol anesthesia: reduction in primary anesthetic use; reduction in emergence and recovery time; and reduction in incidence of awareness with recall.

For pediatric patients, ages 4 and above, the BIS™ Index, one of the BIS™ Advance Monitoring System's output parameters, may be used to guide anesthetic administration of sevoflurane with balanced anesthetic techniques in order to monitor the anesthetic effects on the brain.

The use of the BIS™ Index in pediatric patients, when used with sevoflurane anesthesia, has demonstrated a reduction in primary anesthetic use.

VI. TECHNOLOGICAL CHARACTERISTICS COMPARISON

Table 2: Comparison of Technological Characteristics with the Predicate Device.

Device Characteristics	Subject Device BIS™ Advance pEEG Module	Predicate BISX™/BISX4™Module part of BIS™ Advance Monitoring System (K230693)	Comments
Classification	II	II	Identical
Product Code	OLW OMC, OLT, ORT	OLW, OMC, OLT, ORT	Identical
Fundamental Technology	Acquisition and processing of real-time EEG waveforms and processed EEG parameters	Acquisition and processing of real-time EEG waveforms and processed EEG parameters	Identical
Principle of Operation	EEG signals are transmitted from sensors placed on the patient's head to the Module. The Module filters the data, analyzes it for artifacts, and processes it using digital signal processing techniques, then sends the data to the monitor for display.	EEG signals are transmitted from sensors placed on the patient's head to the Module. The Module filters the data, analyzes it for artifacts, and processes it using digital signal processing techniques, then sends the data to the monitor for display.	Identical

Device Characteristics	Subject Device BIS™ Advance pEEG Module	Predicate BISX™/BISX4™Module part of BIS™ Advance Monitoring System (K230693)	Comments
Regulation Number	882.1400	882.1400	Identical
Prescription/over the counter	Prescription	Prescription	Identical
Intended Population	Adult and pediatric, from age 4 years and up	Adult and pediatric, from age 4 years and up.	Identical
Intended Users	Professionally trained health care providers	Professionally trained health care providers	Identical
Environment of Use	Hospitals or medical facilities providing patient care	Hospitals or medical facilities providing patient care	Identical
Sensors Compatibility	BIS™ Sensors (cleared under K143506)	BIS™ Sensors (cleared under K143506)	Identical
BIS™ Algorithm	4.1	4.1	Identical
ECG Artifact Filtering	Enhanced or legacy, on demand-capability (default Enhanced)	Legacy	Different: The subject device is equipped with the enhanced ECG filtering algorithm in the preprocessing phase of the BIS™ Algorithm
EEG Channels	2 or 4 (single model/enclosure),	BISX™: 2 BISX4™: 2 or 4, depending on connected sensor and monitor capability	Different: Subject device supports both 2 and 4 channels within the same hardware unit; predicate device requires separate units for each configuration
Processed Parameters	SQI EMG SR BC SEF95 MF, SEF 50 ST	SQI EMG SR BC SEF95 MF, SEF 50	Similar: The ST parameter was not produced by the predicate device; it was calculated by the BIS™ Advance Monitor, using data sent from the predicate device. To calculate the ST parameter, the subject device uses the same algorithm that was used by the monitor; therefore,

Device Characteristics	Subject Device BIS™ Advance pEEG Module	Predicate BISX™/BISX4™Module part of BIS™ Advance Monitoring System (K230693)	Comments
			no differences are expected.
Memory	64 GB eMMC	32 MB Flash	Different: The subject device has increased data storage capacity.
Software	Moderate Level of Concern	Basic Documentation Level	Similar: Level of Concern remains unchanged. Different terminology: Under the previous software guidance, it was classified "moderate", whereas the updated 2023 guidance refers to it as "basic documentation level".
Sensor Cable	Terminated to mate with BIS™ Sensors Equipped with DSC converter in the Front-End	Terminated to mate with BIS™ Sensors	Similar: Terminated to mate with BIS™ Sensors. Different: Relocation of the digitization unit (DSC) to the Sensor Cable Front End
Host Cable	Terminated per OEM to mate with OEM Host (Including BIS™ Advance Monitor)	Terminated per OEM to mate with different OEM Hosts (Previously called Monitor Interface Cable (MIC)).	Similar: Terminated per Host Monitor Inlets Different: Different termination on the Module side
Patient Contacting Materials	Sensor connector: Tritan MX711 (white), soft TPU (Texin TXT70A, Blue), Elastollan 1170AFC (strain relief) Cable management system: Polyamide, POM (Velcro strap) FE Cable jacket: TPU, colored gray Clip: POM- Polyoxymethylene (clip), Tail Tape (PVC), SUS 316L(spring), Aluminum (connecting rivet)	SANTOPRENE 8281-75MED OR 281-73MED (for sensor connector side), PVC (for cable jacket)	Different Patient contacting materials The device has successfully passed Biocompatibility tests per ISO 10993-1

Device Characteristics	Subject Device BIS™ Advance pEEG Module	Predicate BISX™/BISX4™Module part of BIS™ Advance Monitoring System (K230693)	Comments
Standards	IEC 60601-1:2005+A1:2012+A2:2020 IEC 60601-1-2:2014+A1:2020 IEC 60601-1-6:2010+A1:2013+A2:2020 IEC 62366-1:2015+A1:2020 IEC 80601-2-26:2019+A1:2024	IEC 60601-1:2005+A1:2012+A2:2020 IEC 60601-1-2:2014+A1:2020 IEC 60601-1-6:2010+A1:2013+A2:2020 IEC 62366-1:2015+A1:2020 IEC 80601-2-26:2019	Similar: Except for the 2024 amendment of the EEG standard (IEC 80601-2-26)

The subject device, **BIS™ Advance pEEG Module**, is substantially equivalent to the predicate device, the BISX™ and BISX™ Modules, previously cleared as part of the BIS™ Advance Monitoring System (K230693). The BIS™ Advance pEEG Module has been developed to replace the predicate modules due to the end-of-life considerations associated with the main components. While the subject device introduces updated hardware and software architecture, it maintains the same indications for use, principle of operation, core functionality, and fundamental scientific technology as the predicate device.

The subject and the predicate devices both acquire and process electroencephalographic (EEG) signals to generate processed EEG parameters, including the Bispectral Index (BIS™), for monitoring patients' level of hypnosis (depth of anesthesia). No changes have been made to the device's intended use, user population, clinical environment, or overall functionality.

The key technological differences between the subject device and the predicate device are as follows:

- **Complete Hardware and Software redesign** driven by the end-of- life of component replacement.
- **Integration of two-channel and four-channel EEG measurement capabilities** into a single device enclosure.
- **Relocation of the digitization unit to the Sensor Cable Front End,** improving signal-to-noise ratio and reducing artifacts such as ESU interference.
- **Hardware platform readiness for future upgrades.**
- **Software redesign** required to interface with redesigned hardware.
- **Enhanced ECG Artifact Detection and Cleaning Algorithm** to support improved signal processing stability.
- **Difference in Patient-Contacting Materials**

These differences do not raise new questions of safety or effectiveness. Performance testing including electrical safety, EMC, software verification and validation, biocompatibility, and performance bench testing, demonstrates that the BIS™ Advance pEEG Module performs equivalently to the predicate

devices. Based on the comparison of technological characteristics and performance data, the subject device is as safe and effective as the predicate devices and is therefore substantially equivalent.

Although the patient-contacting materials of the subject device differ from those of the predicate device, this difference does not raise new questions of safety or effectiveness. The subject device materials were evaluated in accordance with the FDA guidance "Use of International Standard ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process" and the device's identified nature and duration of contact.

A comprehensive biocompatibility assessment was performed, and all testing demonstrated that the subject device materials are biologically safe for their intended use. Testing included the endpoints applicable to the device's contact type, e.g., cytotoxicity, sensitization, irritation, required per ISO 10993-1. All results met acceptance criteria, confirming that the materials do not present additional biological risks compared to the predicate.

Based on the successful completion of biocompatibility testing and the absence of adverse findings, the difference in patient-contacting materials does not affect the device's safety, effectiveness, or overall substantial equivalence.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Performance Testing – Bench:
In accordance with 21 CFR 807.87(g), bench performance testing was conducted on the subject device, the BIS™ Advance pEEG Module, to support a claim of substantial equivalence to the predicate device cleared in K230693 and to demonstrate that the device was designed to meet the design inputs. Verification and validation testing was completed at a system level to ensure safety and effectiveness of the BIS™ Advance pEEG Module.

Non-clinical testing for the BIS™ Advance pEEG Module

- Performance
- Electrical Safety, EMC, Particular Standards
- Human Factors and Usability
- Reliability
- Software
- Cybersecurity
- Hardware
- Mechanical
- Environmental
- Labeling

- Packaging

Additionally, testing illustrated that the subject device complies with the recent amendment of the EEG particular standard:

- IEC 80601-2-26

Biocompatibility Testing:
Biocompatibility testing of the subject device was performed in accordance with "*Use of International Standard ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process" and the device's identified nature and duration of contact.*

Electrical Safety, EMC Testing:
Electrical safety and EMC testing were performed on the subject device. The subject device complies with 60601-1 standard for safety and 60601-1-2 standard for EMC.

Human Factors Evaluation:
A Human Factors assessment was conducted, and the BIS™ Advance pEEG Module was found to be in conformance with EN 62366-1 and IEC 62366-1.

Software Testing:
Software verification and validation testing were conducted and provided as part of this submission as recommended by the FDA Guidance, "*Content of Premarket Submissions for Device Software Functions: Guidance for Industry and Food and Drug Administration Staff*" (issued June 14, 2023).

Cybersecurity Testing:
Cybersecurity testing was conducted and provided as part of this submission as recommended by the FDA Guidance, "*Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions: Guidance for Industry and Food and Drug Administration Staff" (issued February 2026).*

Performance Testing – Animal:

No animal performance testing was required to demonstrate subject device safety and effectiveness.

Performance Testing – Clinical:
No clinical performance testing was required to demonstrate subject device safety and effectiveness.

VIII. CONCLUSION

Based on the information provided in this premarket notification submission, including intended use, device comparisons, and performance testing, the BIS™ Advance pEEG Module meets applicable safety and performance standards and performs as intended in a manner identical to the predicate. The different

technological characteristics do not raise different questions of safety or effectiveness. Therefore, the BIS™ Advance pEEG Module is considered substantially equivalent to the predicate device currently marketed for the same intended use.