December 12, 2024

EB Neuro S.p.A.
℅ Barry Ashar
President
Makromed, Inc.
88 Stiles Road
Salem, New Hampshire 03079

Re: K242832
Trade/Device Name: NExT Station; NExT Station Advanced
Regulation Number: 21 CFR 882.1835
Regulation Name: Physiological Signal Amplifier
Regulatory Class: Class II
Product Code: GWL, OLT, IKN, GWE, GWF, GWJ
Dated: November 12, 2024
Received: November 12, 2024

Dear Barry Ashar:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Patrick Antkowiak -S

for
Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242832

Device Name
NExT Station
NExT Station Advanced

Indications for Use *(Describe)*
The NExT Station and NExT Station Advanced are physiological signal amplifiers intended to be used during Electromyography (EMG) and Evoked Potential (EP) exams to acquire bioelectric signals produced by the patient's central and peripheral nervous system and muscles. The devices include Galileo NT Line software to record and display acquired data to aid the diagnosis and monitoring of potential disorders of the central and peripheral nervous system and muscles.

The devices include an electrical stimulator, an auditory stimulator, and a photic stimulator as accessories that may optionally be used in evoked response analysis.

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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K242832

Special 510(k) SUMMARY

NExT Station and NExT Station Advanced

Date Prepared:	October 18, 2024
Submitter Information	
Company and Manufacturer Name:	EB Neuro S.p.A.
Contact Person:	Name: Barry Ashar Phone: 603.674.9074 Fax:
Device Information	
Trade Name:	NExT Station and NExT Station Advanced
Common Name:	Physiological Signal Amplifier
Classification and Product Code:	21 CFR 882.1835 GWL - Amplifier, Physiological Signal Additional Product Codes: OLT, IKN – EP and EMG GWE, GWF, GWJ – Auditory, Photic and Electrical stimulators
Device Class:	Class II
Predicate Device:	**K133517, Nemus 2 System (Hardware, amplifier) (GWL)** **K142064, Galileo NT Software (OLT)** EB Neuro S.p.A. 21 CFR 882.1835

Device Description	EMG Family devices (NExT Station and NExT Station Advanced) are capable of detecting electrical signals produced by the central and peripheral nervous systems and by striated muscles. In connection with a PC, where the Galileo NT Line software is installed, they allow to perform both spontaneous and evoked electromyographic activity easily and in all their phases. Their fields of application are Electromyography (EMG) and Evoked Potentials (EP). EB Neuro EMG Family devices include all the elements necessary for the acquisition of neurographic signals, for their analog-digital conversion and pre-processing, for audio monitoring, for the delivery of electrical, acoustic and visual stimulation. The functions of user interface, presentation, post-processing, storage, signals archiving and printing and data extracted from them are managed by a PC installed with the Galileo NT Line software. Two versions are available depending on the support where the Medical Device is placed: - "Mobile" is a mobile device placed on a cart, powered at 115V by Isolation Transformer and connected with a PC with Galileo NT Line medical device software running on the PC. - "Portable" is a portable device placed on a desk, powered at 115V by medical power supply and connected with a PC with Galileo NT Line medical device software running on a Laptop PC.
Intended Use:	The NExT Station and NExT Station Advanced are physiological signal amplifiers intended to be used during Electromyography (EMG) and Evoked Potential (EP) exams to acquire bioelectric signals produced by the patient's central and peripheral nervous system and muscles. The devices include Galileo NT Line software to record and display acquired data to aid the diagnosis and monitoring of potential disorders of the central and peripheral nervous system and muscles. The devices include an electrical stimulator, an auditory stimulator, and a photic stimulator as accessories that may optionally be used in evoked response analysis.
Technological Comparison	The subject devices are essentially a bundled together package of our own previously cleared predicate devices. The first predicate device Nemus 2 is an EMG amplifier hardware and the second predicate device Galileo NT is an EMG analysis software. They were previously 510(k) cleared on their own and are now being bundled together as a full EMG system. No new features are added to the subject devices compared to the predicate devices. The subject devices essentially have the same design as

	the predicate devices. Both the subject and predicate devices use very similar components and accessories. The basic operational procedures including system setup, patient preparations, signal acquisition, data storage and analysis are identical between the subject and predicate devices. Subject devices' technological characteristics remain the same as those of the predicate devices. The following changes are made in the subject devices compared to the predicate devices: - Two predicate devices (one hardware, the other software) previously cleared in their own separate 510(k)s are now being combined together as the subject device, with the exact same intended use as the ones of the predicate devices. - Since the subject device now includes the software, it is provided with accessories like PC, keyboard, mouse and screen. Everything is mounted together on a cart or offered as a desktop setup. The predicate hardware device didn't include these. The predicate software device didn't include these as the user was asked to install the software on any platform of their choice. - The predicate hardware device had 2 EMG channels, the subject device has 4 EMG channels. - Some hardware components have been upgraded for better performance, for example, better quality Low Pass Filter for improved noise reduction. - The predicate hardware device included one visual stimulator, the subject device includes three visual stimulators to address user needs. All visual stimulators have passed EMC and Light Safety testing.

Basis for Equivalence	The subject devices are essentially a bundled together package of our own previously cleared predicate devices, with the same intended use and technological characteristics. The first predicate device Nemus 2 is an EMG amplifier hardware and the second predicate device Galileo NT is an EMG analysis software. They were previously 510(k) cleared on their own and are now being bundled together as a full EMG system.
Performance Testing	Due to the enhancements made to the electronic and electrical components, it was necessary to verify the electrical/mechanical/thermal safety and electromagnetic compatibility (EMC) of the subject devices. This was performed using the exact same test methods used for the predicate device using FDA-recognized external standards ANSI/AAMI ES60601-1 and IEC 60601-1-2. LED visual stimulators passed Light

	Safety Testing performed in accordance with EN ISO 15004-2 (Light Hazard Protection) and EN 62471 (Photobiological Safety of Lamps and Lamp Systems). Incremental software enhancements and bug fixes in the subject devices compared to the predicate devices were determined to not have any safety or effective implications on the device. Each incremental released version was subjected to verification testing, at unit, integration and/or system level, as appropriate for the update in the scope of that version. In addition, the subject devices of this 510(k) submission were subjected to a complete and comprehensive V&V testing.

Table 12-1. Side-by-Side Comparison of the Subject Device and Predicate Device

Item	Subject Devices		Predicate Devices		Comments
	NExT Station	NExT Station Advanced	Nemus 2 (K133517)	Galileo NT (K142064)	
Intended Use					
Intended Use	The NExT Station and NExT Station Advanced are physiological signal amplifiers intended to be used during Electromyography (EMG) and Evoked Potential (EP) exams to acquire bioelectric signals produced by the patient's central and peripheral nervous system and muscles. The devices include Galileo NT Line software to record and display acquired data to aid the diagnosis and monitoring of potential disorders of the central and peripheral nervous system and muscles. The devices include an electrical stimulator, an auditory stimulator, and a photic stimulator as	The NExT Station and NExT Station Advanced are physiological signal amplifiers intended to be used during Electromyography (EMG) and Evoked Potential (EP) exams to acquire bioelectric signals produced by the patient's central and peripheral nervous system and muscles. The devices include Galileo NT Line software to record and display acquired data to aid the diagnosis and monitoring of potential disorders of the central and peripheral nervous system and muscles. The devices include an electrical stimulator, an auditory stimulator, and a photic stimulator as	Medical Device intended to acquire bioelectric signals produced by the patient's central and peripheral nervous system and muscles. The acquired signals are transmitted to a PC during recording of neurophysiology examinations. The device may use electrical stimulus, sound stimulus, or visual stimulus for use in evoked response analysis.	Intended to record and display EEG, Video-EEG, LTM, PSG, EMG, EP data acquired from the patient body through EB Neuro acquisition platform, to aid the diagnosis and monitoring of potential disorders of the central and peripheral nervous system and muscles.	Similar. See Note 1.

Item	Subject Devices		Predicate Devices		Comments
	NExT Station	**NExT Station Advanced**	**Nemus 2 (K133517)**	**Galileo NT (K142064)**	
	accessories that may optionally be used in evoked response analysis.	accessories that may optionally be used in evoked response analysis.			
Intended Usage Site	Hospital environments.	Hospital environments.	Hospitals, laboratory, institutions, or other test environments. The device may be placed in Intensive Care Unit or Operating Room for continuous recording.	The device is intended to be used in the clinical and hospital environment (including the hospital room, emergency room, intensive care unit, neuro-intensive care unit, critical care unit).	Same
Intended User	Neurology physicians, Neurophysiopathology technicians under physician's supervision, other physicians such as anesthesiologists, neonatologists and nursing staff of intensive care unit.	Neurology physicians, Neurophysiopathology technicians under physician's supervision, other physicians such as anesthesiologists, neonatologists and nursing staff of intensive care unit.	The user can only be on the order of a physician.	This device is intended to be used by qualified medical practitioners who will exercise professional judgment in using the information.	Same
Design - General					

Item	Subject Devices		Predicate Devices		Comments
	NExT Station	**NExT Station Advanced**	**Nemus 2 (K133517)**	**Galileo NT (K142064)**	
System Configuration	It is a signal acquisition device connected to a PC with Galileo NT software running on the PC. It can be placed on a trolley (mobile version) or on a desk (portable version).	It is a signal acquisition device connected to a PC with Galileo NT software running on the PC. It can be placed on a trolley (mobile version) or on a desk (portable version).	It is a signal acquisition device intended to be connected to a PC with Galileo NT software running on the PC. The PC can be placed on a trolley (mobile version) or on a desk (portable version).	It is a software only device, deployed on a Windows-based PC.	Similar. See Note 2.
Power Supply	115 V medical power supply.	115 V medical power supply.	115 V medical power supply.	N/A	Same
Components and Accessories	Acquisition and stimulation modules Medical AC/DC adapter LAN connection LAN isolator Electrical, visual and audio stimulators Windows PC Keyboard, mouse, printer Trolley Cables	Acquisition and stimulation modules Medical AC/DC adapter LAN connection LAN isolator Electrical, visual and audio stimulators Windows PC Keyboard, mouse, printer Trolley Cables	Acquisition and stimulation modules Medical AC/DC adapter LAN connection Electrical, visual and audio stimulators Cables	Software intended to be deployed on a PC equipped with keyboard, mouse, printer, and mounted on a desktop or trolley.	Similar. See Note 3.
Computer	- Desktop PC - Laptop PC	- Desktop PC - Laptop PC	Intended for: - Desktop PC - Laptop PC	Intended for: - Desktop PC - Laptop PC	Same
Operating System	Windows	Windows	Windows	Windows	Same

Item	Subject Devices		Predicate Devices		Comments
	NExT Station	**NExT Station Advanced**	**Nemus 2 (K133517)**	**Galileo NT (K142064)**	
Software	Resident and runtime downloadable.	Resident and runtime downloadable.	Resident and runtime downloadable.	Resident and runtime downloadable.	Same
Communication Protocol	TCP/IP link on: "wired LAN " ETHERNET/IEEE 802.3	TCP/IP link on: "wired LAN " ETHERNET/IEEE 802.3	TCP/IP link on: "wired LAN " ETHERNET/IEEE 802.3	N/A	Same
Signal Acquisition	Analog to digital conversion at variable sampling rate	Analog to digital conversion at variable sampling rate	Analog to digital conversion at variable sampling rate	N/A	Same
Trigger Input (synchronization to external signal)	TTL LEVEL – negative slope	TTL LEVEL – negative slope	TTL LEVEL – negative slope	N/A	Same
Trigger Output (synchronization for external signal)	TTL signal – active high, 20us duration	TTL signal – active high, 20us duration	TTL signal – active high, 20us duration	N/A	Same
Patient Circuitry Isolation	Patient isolation BF type	Patient isolation BF type	Patient isolation BF type	N/A	Same
Device Dimensions	NExT-AMP Amplifier 190 (L) x 150 (W) x 60 (H) (mm)	NExT-AMP Advanced Amplifier 190 (L) x 150 (W) x 60 (H) (mm)	NeMus 2 Base Unit 170 (L) x 125 (W) x 35 (H) (mm)	N/A	Similar values
Device Weight	NExT-AMP Amplifier ~1 Kg	NExT-AMP Advanced Amplifier ~1 Kg	NeMus 2 Base Unit 0.6 Kg	N/A	Similar values
Design - Acquisition					
Measurement Principle	The device provides acquisition of the	The device provides acquisition of the	The device provides	N/A	Same

Item	Subject Devices		Predicate Devices		Comments
	NExT Station	NExT Station Advanced	Nemus 2 (K133517)	Galileo NT (K142064)	
	physiological signal that is subsequently elaborated on the software on Host PC.	physiological signal that is subsequently elaborated on the software on Host PC.	acquisition of the physiological signal that is subsequently elaborated on the software on Host PC.		
Number of Channels	4 EMG channels	4 EMG channels 8 EP channels	2 EMG channels 20 EP channels	N/A	Similar. See Note 4.
CMRR	>110 dB	> 110 dB	> 100 dB	N/A	Same
Noise	< 0,4 µVrms (0,1Hz - 10kHz) < 0,02 µVrms (0,1Hz - 30Hz)	< 0,4 µVrms (0,1Hz - 10kHz) < 0,02 µVrms (0,1Hz - 30Hz)	< 0.3 µVrms (0.1 – 100 Hz)	N/A	Similar values.
Differential Input Impedance	> 100 MΩ	> 100 MΩ	> 100 MΩ	N/A	Same
Low Pass Filter	10 KHz	10 KHz	20 KHz	N/A	Similar values. See Note 5.
High Pass Filter	0.1 Hz	0.1 Hz	Selectable 0.1 Hz or 10 Hz	N/A	
A/D Conversion	EMG channels: 24 bit	EMG channels: 24 bit EP channels: 24 bit	EMG channels: 24 bit EP channels: 16 bit	N/A	Similar values. See Note 6.
Sampling Rate	Adjustable: 2048, 4096, 8192, 16384, 32768, 65536 Hz	Adjustable: 2048, 4096, 8192, 16384, 32768, 65536 Hz	32768 Hz (EMG ch) 16384 Hz (EP ch)	N/A	Similar values. See Note 7.
Trigger Mode	Free, Auto, Internal, External	Free, Auto, Internal, External	Free, Auto, Internal, External	N/A	Same
Ohmmeter	Measurement of the impedance in all bioelectric channels in	Measurement of the impedance in all bioelectric channels in	Measurement of the impedance in all bioelectric	N/A	Same

Item	Subject Devices		Predicate Devices		Comments
	NExT Station	NExT Station Advanced	Nemus 2 (K133517)	Galileo NT (K142064)	
	the range 1-100 KOhm with precision of +/- 10%	the range 1-100 KOhm with precision of +/- 10%	channels in the range 1-100 KOhm with precision of +/- 10%		
Electrical Stimulation					
Somatosensory (electrical) stimulator	Yes	Yes	Yes	N/A	Same
Type	Constant Current	Constant Current	Constant Current	N/A	Same
No. of Outputs	2	2	1	N/A	Similar values. See Note 8.
Max Output	100 mA	100 mA	100 mA	N/A	Same
Pulse Width	0.05 – 1 ms	0.05 – 1 ms	0.05 – 1 ms	N/A	Same
Mode	Single, train	Single, train	Single, train	N/A	Same
Acoustic Stimulation					
Audio stimulator	Yes	Yes	Yes	N/A	Same
Output mode	Tone, click or noise	Tone, click or noise	Tone, click or noise	N/A	Same
Sound pressure	Tone/click: 32-132 dB SPL Noise: [-40 to +10] dB REL	Tone/click: 32-132 dB SPL Noise: [-40 to +10] dB REL	Tone/click: 32-132 dB SPL Noise: [-40 to +10] dB REL	N/A	Same
Phase	Compressed / Rarefied / Alternating	Compressed / Rarefied / Alternating	Compressed / Rarefied / Alternating	N/A	Same
Signal frequency	125-8000 Hz	125-8000 Hz	125-8000 Hz	N/A	Same
Click width	20-1000 µs	20-1000 µs	1-100 µs	N/A	Similar values.

Item	Subject Devices		Predicate Devices		Comments
	NExT Station	**NExT Station Advanced**	**Nemus 2 (K133517)**	**Galileo NT (K142064)**	
Stimulus	Left, right, binaural	Left, right, binaural	Left, right, binaural	N/A	Same
Visual Stimulation					
Visual Stimulator	- Flash LED Stimulator - Lens Goggles Stimulator II - Pattern Monitor	- Flash LED Stimulator - Lens Goggles Stimulator II - Pattern Monitor	- Flash LED Stimulator	N/A	Similar. See Note 9.
Performance Standards					
Electrical, Mechanical and Thermal Safety	ANSI AAMI 60601-1	ANSI AAMI 60601-1	ANSI AAMI 60601-1	N/A	Same
Electromagnetic Compatibility	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	N/A	Same
EMG and EP Requirements	IEC 60601-2-40	IEC 60601-2-40	IEC 60601-2-40	N/A	Same
Light Hazard Protection	EN ISO 15004-2	EN ISO 15004-2	EN ISO 15004-2	N/A	Same
Photobiological Safety of Lamps and Lamp Systems	EN 62471	EN 62471	EN 62471	N/A	Same
Medical Device Software	IEC 62304	IEC 62304	IEC 62304	IEC 62304	Same
Medical Device Risk Management	ISO 14971	ISO 14971	ISO 14971	ISO 14971	Same

Note 1: The subject devices are essentially a bundled package of the two predicate devices. As a result, their intended use is a combination of the intended uses of the predicate devices.

Note 2: The subject devices are essentially a bundled package of the two predicate devices. As a result, their system configuration is a combination of the system configuration of the predicate devices.
Note 3: The subject devices are essentially a bundled package of the two predicate devices. As a result, their components and accessories are a combination of the components and accessories of the predicate devices.
Note 4: Difference in the number and type of channels address different market needs and preferences, they do not raise any additional questions of safety or effectiveness.
Note 5: Subject devices remove high frequency components for effective removal of noise and artifacts..
Note 6: Subject devices have same EMG A/D conversion resolution, have higher EP A/D conversion resolution.
Note 7: Subject devices have maximum sampling frequency higher than predicate devices, ensuring a higher fidelity digitization.
Note 8: Additional stimulation output on the subject devices has no impact on safety or effectiveness.
Note 9: Additional optional visual stimulators available with the subject devices were tested and verified to conform to the EMC requirements of IEC 60601-1-2 requirements as well as to the Light Safety requirements of EN ISO 15004-2 and EN 62471. They have no impact on safety or effectiveness.

CONCLUSION

The subject devices (NExT Station and NExT Station Advanced) and the predicate devices (Nemus 2 and Galileo NT) have identical intended use /indication for use. The subject devices are essentially a bundled together package of previously cleared predicate devices. The first predicate device Nemus 2 is an EMG amplifier hardware and the second predicate device Galileo NT is an EMG analysis software. They were previously 510(k) cleared on their own and are being bundled together as a full EMG system.

Subject devices' technological characteristics remain the same as those of the predicate devices. The basic operational procedures including system setup, patient preparations, signal acquisition, data storage and analysis are identical between the subject and predicate devices.

Both the subject and predicate device use very similar components and accessories. The differences in their configurations due to the enhancements listed in section 12.5 above do not have any impact on the safety and effectiveness of the subject device.

The subject devices do not introduce any new safety considerations in comparison to the predicate devices. All identified differences between the two systems are minor and without any known impact on safety or efficacy.

Based on the information and supporting documentation provided in this premarket notification, the subject devices (NExT Station and NExT Station Advanced) are substantially equivalent to the cited predicate devices (Nemus 2 and Galileo NT).