November 25, 2023

Anumana, Inc.
Animesh Agarwal
VP of Product Management
1 Main St.
East Arcade, 4th Floor
Cambridge, Massachusetts 01242

Re: K233160
Trade/Device Name: NeuTrace EP Mapping System v.2.1
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable diagnostic computer
Regulatory Class: Class II
Product Code: DQK
Dated: September 27, 2023
Received: September 27, 2023

Dear Animesh Agarwal:

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.

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,

Aneesh S. Deoras -S

Aneesh Deoras
Assistant Director
Division of Cardiac Electrophysiology,

Diagnostics and Monitoring Devices
Office of Cardiovascular 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)*
K233160

Device Name
NeuTrace EP Mapping System v.2.1

Indications for Use *(Describe)*
The NeuTrace EP Mapping System v2.1 is indicated for catheter-based cardiac electrophysiological (EP) procedures. The NeuTrace EP Mapping System v2.1 provides information about the electrical activity of the heart and about catheter location during the procedure. The system can be used on patients who are eligible for a conventional electrophysiological procedure in the right atrium. The system has no special contraindications.

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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510k Summary
K233160
Neutrace EP Mapping System v.2.1

510(k) Number	K233160
510(k) Type	Traditional
Date Prepared	November 22, 2023
Applicant:	Anumana Inc. One Main Street, Suite 400 East Arcade 4th Floor, Cambridge MA 02142
Contact Persons:	Suzanne Goodman Vice President of Quality and Regulatory Sgoodman@nference.net (919) 608-6082 Animesh Agarwal Vice President of Product Management animesh.agarwal@nference.net (267) 945-3387
Trade Name	NeuTrace EP Mapping System v.2.1
Common Name	Programmable diagnostic computer
Class	II
Regulation Number	21 CFR 870.1425 Computer, diagnostic, programmable
Product Code	DQK
Predicate Device	CARTO 3 EP Navigation System (K133916)
Reference Device:	EnSite X EP System (K202066)

Device Description

The NeuTrace EP Mapping System v2.1 (NeuTrace System) is an advanced 3D electroanatomical mapping (EAM) and analysis system capable of:

- Displaying catheter location during electrophysiology mapping procedures
- Displaying 3D images of cardiac structures
- Displaying cardiac activity signals as waveforms (ECGs and EGMs)
- Displaying derived voltage and time metric overlays over cardiac models - including Peak-to-Peak Voltage, Local Activation Time (LAT), Fractionation, and Minimum dV/dt

The NeuTrace System comprises the following software and hardware components:

- NeuTrace Workstation
- Window field generator
- System control unit
- System interface unit
- Interface switches and connection cables
- NeuTrace Software Application v2.1
- NeuTrace Streaming Application Software v2.0

The NeuTrace System is used together with compatible recording systems and compatible catheters listed in the device labeling to perform its intended use to support electrophysiology procedures in the right atrium.

Indications For Use

The NeuTrace EP Mapping System v2.1 is indicated for catheter-based cardiac electrophysiological (EP) procedures. The NeuTrace EP Mapping System v2.1 provides information about the electrical activity of the heart and about catheter location during the procedure. The system can be used on patients who are eligible for a conventional electrophysiological procedure in the right atrium. The system has no special contraindications.

Predicate Comparison

The predicate device chosen for the NeuTrace EP Mapping System v2.1 (NeuTrace System) is the Biosense Webster CARTO 3 EP Navigation System (K133916). The selected reference device for the NeuTrace System is the Abbott EnSite X EP System (K202066). The NeuTrace System has the same intended use, technological characteristics, and principles of operation as the CARTO 3 EP Navigation System. The EnSite X EP System was added as a reference device to the NeuTrace System because it is a Class II electroanatomical navigation and mapping system under the same regulatory classification, utilizes similar magnetic-based localization, and has

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similar catheter compatibility. The NeuTrace System is compared to the predicate and reference devices in the table below.

	NeuTrace EP Mapping System v2.1 (NeuTrace System) Subject of this 510(k)	Biosense Webster's CARTO 3 EP Navigation System (CARTO 3 System) (Predicate Device)	EnSite X EP System (Reference Device)	Comments
510(k)	K233160	K133916	K202066	N/A
Device class	II	II	II	Same
Classification	Programmable diagnostic-computer Class II; 21 CFR, 870.1425	Programmable diagnostic-computer Class II; 21 CFR, 870.1425	Programmable Diagnostic Computer Class II; 21 CFR 870.1425	Same
Product code	DQK	DQK	DQK	Same
Indications/ Intended use	The NeuTrace EP Mapping System v2.1 is indicated for catheter-based cardiac electrophysiological (EP) procedures. The NeuTrace EP Mapping System v2.1 provides information about the electrical activity of the heart and about catheter location during the procedure. The system can be used on patients who are eligible for a conventional electrophysiological procedure in the right atrium. The system has no special contraindications.	The intended use of the CARTO 3 System is catheter-based cardiac electrophysiological (EP) procedures. The CARTO 3 System provides information about the electrical activity of the heart and about catheter location during the procedure. The system can be used on patients who are eligible for a conventional electrophysiological procedure. The system has no special contraindications.	The EnSite™ X EP System is a suggested diagnostic tool in patients for whom electrophysiology studies have been indicated. The EnSite™ X EP System provides information about the electrical activity of the heart and displays catheter location during conventional electrophysiological (EP) procedures.	Same

	NeuTrace EP Mapping System v2.1 (NeuTrace System) Subject of this 510(k)	Biosense Webster's CARTO 3 EP Navigation System (CARTO 3 System) (Predicate Device)	EnSite X EP System (Reference Device)	Comments
Intended users	EP's and EP lab staff trained on the use of the system	EP's and EP lab staff trained on the use of the system	EP's and EP lab staff trained on the use of the system	Same
System Components	1. Sensor Interface Unit & Sensor Control Unit 2. Workstation with Graphic User Interface 3. Keyboard, and mouse 4. Power Supply 5. Monitor 6. Window Field Generator 7. Interface switches and conn. cables	1. Patient Interface Unit (PIU) 2. Workstation with Graphic User Interface 3. Keyboard, and mouse 4. Power Supply 5. Monitor 6. Location Pad 7. Patches & Connection Box 8. Foot pedals	1. Amplifier with associated modules 2. Workstation with monitors and isolation transformer 3. Optional printer 4. Field Frame Generator 5. Catheter Input Modules 6. Patient Reference Sensors 7. ECG cable.	Similar. The component differences do not affect the intended use.
Principles of operation/ location technology	Magnetic-based localization Secondary: n/a	Magnetic-based localization Secondary: impedance-based localization	Magnetic-Based localization Secondary: impedance-based localization	Less accurate impedance mode is not required for the same intended use
Compatible Catheters	1. FlexAbility™ Ablation Catheter, Sensor Enabled™ 2. n/a	1.Specialized catheters with integrated magnetic sensor 2.Conventional catheters (w/o magnetic sensors)	1.Specialized catheters with integrated magnetic sensor 2.Conventional catheters (w/o magnetic sensors)	1.Same 2. Not req'd for the same intended use.
Acquisition of data points	Manual or automatic	Manual or automatic	Manual or automatic	Same

	NeuTrace EP Mapping System v2.1 (NeuTrace System) Subject of this 510(k)	Biosense Webster's CARTO 3 EP Navigation System (CARTO 3 System) (Predicate Device)	EnSite X EP System (Reference Device)	Comments
3D Geometry mapping	Yes	Yes	Yes	Same
Electrograms for activation and voltage mapping	Yes. Local Activation Time maps, voltage maps, propagation maps, & fractionation maps	Yes, Local Activation Time maps, voltage maps, impedance maps, and propagation maps	Yes, Local Activation Time maps, voltage maps, impedance maps, and propagation maps	Similar - NeuTrace does not include the lower accuracy Impedance maps
Ablation lesion visualization and tagging	Yes	Yes, optional (Visitag Module)	Yes	Same
Compatible with an RF generator	Yes	Yes	Yes	Same

Performance Data

Bench testing and a GLP animal study were performed to assure the NeuTrace EP Mapping System v2.1 meets all specifications and user requirements and to demonstrate substantial equivalence with the predicate and reference devices.

Bench Testing

- Software Verification and Validation
- Hardware Verification including 4-hour shift and drift testing and intrinsic time delay testing
- Cybersecurity Risk Management & Testing
- EMC/EMI testing per IEC 60601-1 and IEC 60601-1-2
- NeuTrace-EnSite accuracy and equivalency testing
- NeuTrace-CARTO geometry and mapping equivalency analyses

GLP Animal Study

- System performance verification and validation for accuracy, shift, drift, geometry, peak-to-peak voltage maps, local activation time maps, fractionation maps, and summative usability.

Overall, the NeuTrace EP Mapping System v2.1 passed all testing and met all design specifications and user requirements. Ground-truth accuracy was statistically demonstrated as < 1mm, shift < 1 mm, and drift < 2mm. Equivalent generation of 3D

geometries and maps compared with the predicate CARTO 3 System was demonstrated. Equivalent accuracy and performance compared with the reference EnSite X System using the FlexAbility™ Ablation Catheter, Sensor Enabled™ catheter was demonstrated.

Statement of Equivalence

The NeuTrace EP Mapping System v2.1, Biosense Webster's CARTO 3 EP Navigation System (predicate device), and EnSite X EP System (reference device) all have substantially equivalent intended use, technological characteristics, principles of operation, and ground-truth performance. Bench test data and In-vivo preclinical data for the subject device, predicate device, and reference device have been performed to demonstrate substantial equivalence and ground-truth performance. The testing completed and submitted in this Traditional 510(k) provides objective evidence the NeuTrace System is at least as safe and effective and substantially equivalent to the CARTO 3 System.