October 6, 2023

Intelligent Ultrasound Limited
Bhaskar Chikkanna
Head of Regulatory Affairs
Floor 6a, Hodge House, 114-116 St Mary Street
Cardiff, CF101DY
United Kingdom

Re: K232787
Trade/Device Name: ScanNav Anatomy Peripheral Nerve Block
Regulation Number: 21 CFR 868.1980
Regulation Name: Real-Time Ultrasound Anatomy Visualization And Labeling Device For Ultrasound Guided Regional Anesthesia
Regulatory Class: Class II
Product Code: QRG
Dated: September 11, 2023
Received: September 11, 2023

Dear Bhaskar Chikkanna:

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,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Sleep Disordered Breathing, Respiratory and Anesthesia 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232787

Device Name
ScanNav Anatomy Peripheral Nerve Block

Indications for Use *(Describe)*
ScanNav Anatomy Peripheral Nerve Block is indicated to assist qualified healthcare professionals to identify and label the below mentioned anatomy in live ultrasound images in preparation for ultrasound guided regional anesthesia prior to needle insertion for patients 18 years of age or older.
The highlighting of structures in the following anatomical regions is supported:
- Axillary level brachial plexus
- Erector spinae plane
- Interscalene level brachial plexus
- Popliteal level sciatic nerve
- Rectus sheath plane
- Sub-sartorial femoral triangle / Adductor canal
- Superior trunk of brachial plexus
- Supraclavicular level brachial plexus
- Longitudinal suprainguinal fascia iliaca plane
- Femoral block

ScanNav Anatomy Peripheral Nerve Block is an accessory to compatible general-purpose diagnostic ultrasound systems.

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
K232787

September 27, 2023

Applicant details:

Applicant Name: Intelligent Ultrasound Limited
Applicant Address: Floor 6a, Hodge House, 114-116 St Mary Street, Cardiff, UK
Applicant Contact Name: Bhaskar Chikkanna
Applicant Contact Number: +442920756534
Applicant Contact Email: bhaskar.chikkanna@intelligentultrasound.com

Device details:

Device Trade Name: ScanNav Anatomy Peripheral Nerve Block
Common Name: Software as a Medical Device
Classification: Class II
Regulation Number: 21 CFR 868.1980
Product Code: QRG

Predicate Device details:

Device Trade Name: ScanNav Anatomy Peripheral Nerve Block
Predicate #: DEN220024
Product code: QRG

Device description summary:

ScanNav Anatomy Peripheral Nerve Block is a software as a medical device (SaMD) which assists qualified healthcare professionals to identify and label relevant anatomical structures in live ultrasound images in preparation for ultrasound guided regional anesthesia prior to needle insertion for patients 18 years of age or older.

The device receives ultrasound images in real-time from a compatible general-purpose ultrasound machine. It processes these images using deep learning artificial intelligence algorithms and highlights relevant anatomical structures. The ultrasound machine display remains unaffected, and the highlighting is only displayed on a general-purpose panel PC provided with the device.

Intended use/Indications for use:

ScanNav Anatomy Peripheral Nerve Block is indicated to assist qualified healthcare professionals to identify and label the below mentioned anatomy in live ultrasound images in preparation for ultrasound guided regional anesthesia prior to needle insertion for patients 18 years of age or older.

The highlighting of structures in the following anatomical regions is supported:
- Axillary level brachial plexus
- Erector spinae plane
- Interscalene level brachial plexus
- Popliteal level sciatic nerve
- Rectus sheath plane
- Sub-sartorial femoral triangle / Adductor canal
- Superior trunk of brachial plexus
- Supraclavicular level brachial plexus
- Longitudinal suprainguinal fascia iliaca plane
- Femoral block

ScanNav Anatomy Peripheral Nerve Block is an accessory to compatible general-purpose diagnostic ultrasound systems.

Substantial Equivalence

Attributes	Predicate (DEN220024)	Modified device	Comments
Intended use	ScanNav Anatomy Peripheral Nerve Block is intended to assist in the identification and labelling of anatomical structures in live ultrasound images.	ScanNav Anatomy Peripheral Nerve Block is intended to assist in the identification and labelling of anatomical structures in live ultrasound images.	No change
Indications for use	ScanNav Anatomy Peripheral Nerve Block is indicated to assist qualified healthcare professionals to identify and label the below mentioned anatomy in live ultrasound images in preparation for ultrasound guided regional anesthesia prior to needle insertion for patients 18 years of age or older. The highlighting of structures in the following anatomical regions is supported: • Axillary level brachial plexus • Erector spinae plane • Interscalene level brachial plexus • Popliteal level sciatic nerve • Rectus sheath plane • Sub-sartorial femoral triangle / Adductor canal • Superior trunk of brachial plexus	ScanNav Anatomy Peripheral Nerve Block is indicated to assist qualified healthcare professionals to identify and label the below mentioned anatomy in live ultrasound images in preparation for ultrasound guided regional anesthesia prior to needle insertion for patients 18 years of age or older. The highlighting of structures in the following anatomical regions is supported: • Axillary level brachial plexus • Erector spinae plane • Interscalene level brachial plexus • Popliteal level sciatic nerve • Rectus sheath plane • Sub-sartorial femoral triangle / Adductor canal • Superior trunk of brachial plexus	Addition of Femoral block to the list of supported ultrasound guided regional anesthesia procedures

	• Supraclavicular level brachial plexus • Longitudinal suprainguinal fascia iliaca plane ScanNav Anatomy Peripheral Nerve Block is an accessory to compatible general-purpose diagnostic ultrasound systems.	• Supraclavicular level brachial plexus • Longitudinal suprainguinal fascia iliaca plane • **Femoral** ScanNav Anatomy Peripheral Nerve Block is an accessory to compatible general-purpose diagnostic ultrasound systems.	
Intended users	Qualified healthcare professionals	Qualified healthcare professionals	No change
Intended use environment	Professional healthcare environment	Professional healthcare environment	No change
Technology/Operating principle	Machine learning based artificial intelligence in combination with image processing algorithms	Machine learning based artificial intelligence in combination with image processing algorithms	No change
Device hardware (panel PC and cables)	Panel PC model IUP10W33M Ac/Dc power cord 2m shielded HDMI cable Optional: external battery unit with power supply	Panel PC model IUP10W33M Ac/Dc power cord 2m shielded HDMI cable Optional: external battery unit with power supply	No change
Labelling (incl. instructions for use)	Instructions for use v1.0 Device labelling	Instructions for use v2.0 Device Labelling	Labelling updated to reflect the changes to the indications for use with new nerve block.

Summary of Clinical/Non-Clinical tests:

The device change subject to this 510(k) has undergone non-clinical tests and accuracy and safety validation tests. The non-clinical test results show that the device has met the predefined acceptance criteria and has passed all tests without any unresolved anomalies. The accuracy and safety validation tests carried out using the established test protocols have testified that the addition of femoral nerve block has met the established acceptance criteria and the device continues to provide reasonable assurance of safety and effectiveness. No new risks have been identified with this device change. The results are summarized in the table below.

Verification/Validation Methods	**Acceptance Criteria**	**Summary of results**
Femoral Block – Safety and Accuracy validation. Established protocol and acceptance criteria same as that used for the predicate device.	FP rate: Mis-identification rate of safety critical anatomical structures in the indicated procedures is less than 5%. Accuracy (TP+TN) rate: Correct highlighting of safety critical anatomical structures in the indicated procedures at least 80% of the time. FN rate: non-identification rate of safety critical anatomical structures in the indicated procedures is less than 15%.	1.1% (2 out of 183 scans) 96.7% (177 out of 183 scans) 2.2% (4 out of 183 scans)
Software tests Established test cases and protocol same as that used for the predicate device.	Unit test Integration test Fault Injection test Endurance test Use case test Software system level test Requirements traceability test	All software tests have been successfully completed without any anomalies

Conclusion:

The subject device and the predicate device have the same intended use and the technological differences do not raise different questions of safety and effectiveness.