October 18, 2022

Intelligent Ultrasound Limited
% Allison Kumar
Regulatory Consultant
Arina Consulting
27 Hilltop Dr
San Carlos, CA 94070

Re: DEN220024
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: April 7, 2022
Received: April 8, 2022

Dear Allison Kumar:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the ScanNav Anatomy Peripheral Nerve Block, a prescription device under 21 CFR Part 801.109 with the following 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

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

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the ScanNav Anatomy Peripheral Nerve Block, and substantially equivalent devices of this generic type, into Class II under the generic name real-time ultrasound anatomy visualization and labeling device for ultrasound guided regional anesthesia.

FDA identifies this generic type of device as:

Real-time ultrasound anatomy visualization and labeling device for ultrasound guided regional anesthesia. This device provides real-time interpretation and enhanced visualization of live ultrasound images by highlighting anatomical landmarks in preparation for performing regional anesthesia.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On April 8, 2022, FDA received your De Novo requesting classification of the ScanNav Anatomy Peripheral Nerve Block. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the ScanNav Anatomy Peripheral Nerve Block into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request FDA has determined that, for the previously stated indications for use, the ScanNav Anatomy Peripheral Nerve Block can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks to Health	**Mitigation Measures**
Adverse events due to inaccurate location identification for ultrasound guided procedures	Clinical performance testing Human factors testing Software verification, validation, and hazard analysis Labeling
Users without expertise operating the device leading to adverse events or ineffective procedure	Labeling

Procedure delay due to corruption in image transfer or software failure	Clinical performance testing Software verification, validation, and hazard analysis

In combination with the general controls of the FD&C Act, the real-time ultrasound anatomy visualization and labeling device for anesthesiology is subject to the following special controls:

(1) Clinical performance testing under anticipated conditions of use must evaluate the location accuracy of anatomical landmarks identified by the device.

(2) Human factors testing must demonstrate that the user can correctly use the device to identify anatomical structures, based solely on reading the instructions for use.

(3) Software verification, validation, and hazard analysis must be performed, including demonstrated compatibility with ultrasound devices labeled to be compatible with the device.

(4) Labeling must include
   (i) The recommended training for safe use of the device;
   (ii) Pertinent details of the clinical data collected to evaluate the performance of the device; and
   (iii) A warning against over-reliance on device output.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the real-time ultrasound anatomy visualization and labeling device for ultrasound guided regional anesthesia they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Annie Abraham at 240-402-5219.

Sincerely,

Denise L. Hampton -S

for Malvina B. Eydelman, M.D.
Director
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health