DE NOVO CLASSIFICATION REQUEST FOR SCANNAV ANATOMY PERIPHERAL NERVE BLOCK

REGULATORY INFORMATION

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.

NEW REGULATION NUMBER: 21 CFR 868.1980

CLASSIFICATION: Class II

PRODUCT CODE: QRG

BACKGROUND

DEVICE NAME: ScanNav Anatomy Peripheral Nerve Block

SUBMISSION NUMBER: DEN220024

DATE DE NOVO RECEIVED: April 25, 2022

SPONSOR INFORMATION:

Intelligent Ultrasound Limited
114-116 St. Mary Street
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Glamorganshite, United Kingdom
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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.

LIMITATIONS

The sale, distribution, and use of the ScanNav Peripheral Nerve Block are restricted to prescription use in accordance with 21 CFR 801.109.

The device is not intended to be used as a stand-alone diagnostic device.

The device should be used by qualified healthcare professionals with the skills and expertise to independently perform ultrasound guided regional anesthesia procedures.

The device output does not reduce the operator's responsibility for informed clinical judgement and best clinical procedure.

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

ScanNav Anatomy Peripheral Nerve Block is a software medical device which assists anesthetists and other qualified healthcare professionals in the identification of anatomical structures within ultrasound images during ultrasound-guided regional anesthesia (UGRA) procedures by highlighting the relevant anatomical structures in real-time.

Figure 1: The display screen with anatomical features highlighted

Highlighting colors as follows:

Arteries	- Red
Bones	-Cyan
Bowel	-Brown
Fascial planes	- Orange
Lung	-Brown
Muscles	-Green
Nerve	-Yellow
Pleural line	-Purple

The device performs the highlighting by using deep learning artificial intelligence technology based on convolutional neural networks (CNNs). These deep-learning models generate a colored overlay that allows the user to identify the specific anatomical structures of interest for the procedure. A separate monitor displays the highlighted images as an overlay on top of the ultrasound image, so the original view from the ultrasound machine is not affected. The deep learning models are locked, and they do not continue to learn in the field.

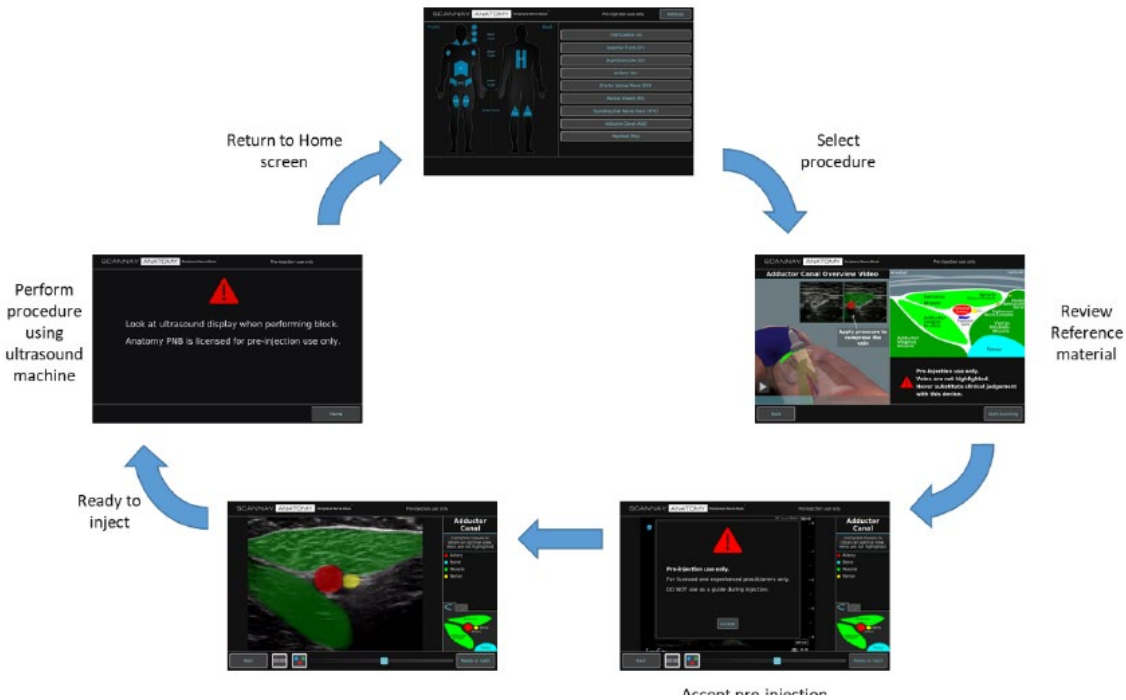
The device interfaces with ultrasound machine with an external monitor output that meets the compatibility requirements. The ScanNav Anatomy Peripheral Nerve Block is run on a mobile computing platform (a commercial off the shelf panel PC) performing the processing with an integrated touchscreen monitor to display the user interface and anatomy highlighting

The Software as a Medical Device is packaged with a tablet PC, power cable, compatible plug, and mounting bracket and instructions for mounting the tablet to the ultrasound host. This acts as a separate monitor to display the highlighted images as an overlay on top of the ultrasound image, so the original view from the ultrasound machine is not affected. The ScanNav Anatomy Peripheral Nerve Block system is composed of a

software medical device and other non-medical devices such as a panel PC, power supply, an HDMI interface cable and a VESA mount as outlined in the figures below:

Figure 2: ScanNav Anatomy Peripheral Nerve Block system connected to Ultrasound scanning machine

Figure 3: High level workflow from block selection to ready to inject anesthetics



SUMMARY OF NONCLINICAL/BENCH STUDIES

ELECTROMAGNETIC CAPABILITY & ELECTRICAL SAFETY

Electrical safety and electromagnetic compatibility testing has been performed per IEC 60601-1-12 Edition 1.1 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment, and IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests. The test results support electrical safety and electromagnetic compatibility.

MAGNETIC RESONANCE (MR) COMPATIBILITY

The subject device is considered MR Unsafe. Appropriate MR safety symbol is included in the labeling.

SOFTWARE

The ScanNav Anatomy Peripheral Nerve Block software documentation was reviewed according to the FDA Guidance document, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, issued May 11, 2005. The software was found to have a Major Level of Concern, because failure or latent flaw could directly result in death or serious injury to the patient prior to risk mitigation. The software documentation included management of cybersecurity and:

1. Software Description
2. Device Hazard Analysis
3. Software Requirements Specification
4. Architecture Design Chart
5. Software Design Specification
6. Traceability Analysis
7. Software Development Environment Description
8. Verification and Validation Documentation
9. Revision Level History
10. Unresolved Anomalies

The software documentation provided in support of the ScanNav Anatomy Peripheral Nerve Block was found to be acceptable.

HUMAN FACTORS TESTING

Thirty (30) anesthesiologists participated in this summative usability validation study starting on February 11, 2022, and completing on February 17, 2022. The study took place in a simulated interventional procedural lab setting at (b) (4) in (b) (4) (b) (4), USA.

This study had two cohorts:

• One cohort consisted of 15 Expert Anesthesiologists competent in independently performing UGRA.
• One cohort consisted of 15 Trainee Anesthesiologists undergoing training for UGRA procedures

All study participants completed the essential and critical tasks.

The study participants completed the following three parts of the study:

1. Performance-based use scenario tasks and associated root cause analysis (RCA), when needed
2. Knowledge Task and Labeling Validation and associated root cause analysis (RCA), when needed
3. Interview/subjective discussion

The data obtained during the summative study were analyzed to determine whether any aspect of the final design of the UI were implicated or pointed out by test participants as a source of difficulties with use, close call, use error, or task failure. The analysis did not find any UI design issues that might impact the safe and effective use of the device. No issues were found that required reconsideration or major modification of the UI design. There were no patterns of use failures, confusion, or difficulties.

SUMMARY OF CLINICAL INFORMATION

Study was carried out over (b) (4) days at Oregon Health & Science University (OHSU), Portland, USA in May 2021.

Study Objective – To gather evidence on the clinical benefit of ScanNav Anatomy PNB for identification of anatomical structures during UGRA scanning, in particular:

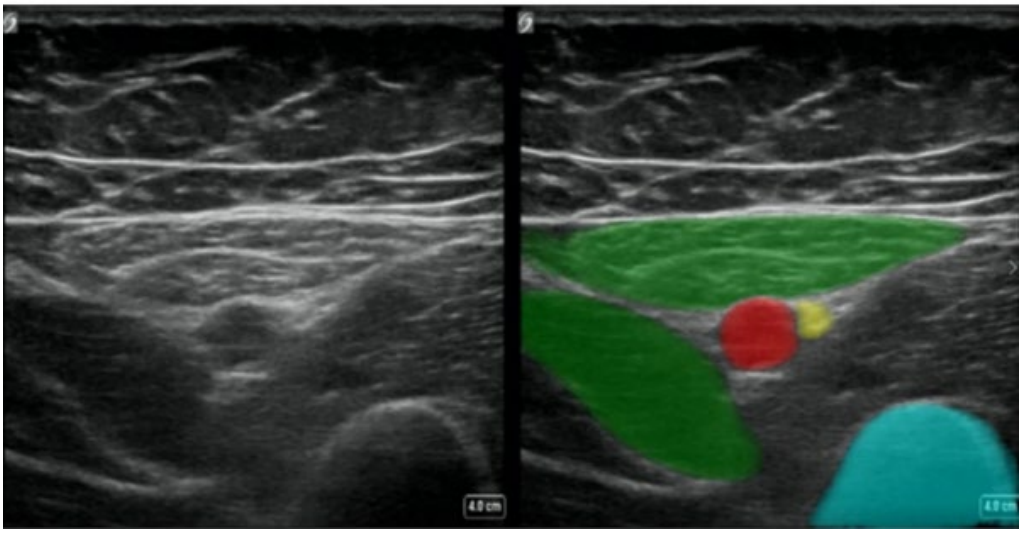
a. Assess the benefits of the device to intended users when supervising a trainee who is performing UGRA scanning.
b. Assess the benefits of the device when intended users perform UGRA scanning.
c. Assess risk mitigation by the intended users when performing UGRA scanning.

Clinical Validation Study to assess Performance and predict Adverse Events:

A single center, prospective validation study [IU2021_AG_07] in the US was conducted on 40 volunteers by the intended users for the specified 9 block regions. The aim of the study was to assess and quantify the correct/incorrect highlighting of anatomical structures associated with subject device during UGRA scanning. The Primary endpoint was Frequency of misidentification of structures [%of total, per anatomical region] with ScanNav Anatomy PNB highlighting. Secondary outcome measures were frequency of correct identification of structures, and frequency of non-identification of structures as well as frequency of safety issues and probable adverse events. Clinicians scanning were anesthesiologists competent to perform independent UGRA. Sonosite Xport and SonoSite PX were used. 10 second scene clips were taken prior to "optimum block" image acquisition. Eighty 10s scene clips were acquired and ten 10s non-scene clips were acquired as well for analyses.

Post-hoc, device output of device was incorporated for each scene. Three expert anesthesiologists in UGRA viewed clips side by side to assess safety and performance of Anatomy PNB.

Figure 4: Example review video of side-by-side captured ultrasound and Scan Nav Anatomy PNB



Experts answered questions on performance of highlighting by device to determine TP, TN, FP, and FN, AEs [PONS, Pneumothorax, LAST, Block failure. Majority opinion [2/3] determined above rates.

Nerve block procedures were not performed as part of the study, therefore the ability of the device to mitigate risks associated with adverse events are unknown.

Using the following definitions below, performance was quantified for each block.

Measure	Answers (2/3 majority)	Assessment	Classification
TP	(b) (4)	(b) (4)	Correct identification
TN			Not visible
FP			Mis-identification
FN			Non-identification
Error			Overall error
Safety Issue			Safety issue
Adverse Event			Adverse event
Block failure			Block failure

Non-scenes	(b) (4)	(b) (4)	Non-scene

Primary Endpoint Analyses:

Block- all views	Exact FP Rate (Misidentification)	Percent
Axillary	0.003	0.3 %
ESP	0.000	0%
IS	0.013	1.3%
Pop	0.006	0.6%
RS	0.032	3.2%
Adductor	0.000	0%
ST	0.052	5.2%
SC	0.008	0.8%
SFIC	0.219	21.9%

Secondary endpoint analyses:

ScanNav Anatomy PNB highlighting

a) Frequency of correct identification of structures (>=80% of total)

Block- all views	Exact Accuracy Rate (TP+TN)	Percent
Axillary	0.977	97.7%
ESP	0.888	88.8%
IS	0.941	94.1%
Pop	0.981	98.1%
RS	0.968	96.8%
Adductor	0.904	90.4%
ST	0.909	90.9%
SC	0.983	98.3%
SFIC	0.762	76.2%

AEs Rate: A

Adverse Event Rate

The secondary endpoint was defined as:

ScanNav Anatomy PNB Adverse Events: Frequency of highlighting risking an adverse event (<=5% of total)

Block	PONS risk	LAST risk	Pneumothorax Risk	Peritoneum risk
Axillary	(b) (4)	(b) (4)	n/a	n/a
IS		n/a	n/a	n/a
Pop		(b) (4)	n/a	n/a
Add			n/a	n/a
ST		n/a	n/a	n/a
SC		n/a	(b) (4)	n/a
ESP	n/a	n/a		n/a
RS	n/a	n/a	n/a	(b) (4)
SFIC	n/a	(b) (4)	n/a	n/a

The study did not include the nerve block procedure, and there is no actual data on the potential adverse events associated with the procedure

Non-Scene analyses were as following:

Risk of mistaking an incorrect view as a correct view	Present
Increased	(b) (4)
No change	
Reduced	
No Consensus	

They concluded that in 70% of the cases, the highlighting significantly reduces the risk of mistaking an incorrect site for the correct block where as incorrect highlighting increased the risk in (b) (4)

HF Study Design

To provide evidence for the clinical benefits of ScanNav Anatomy PNB, Intelligent Ultrasound ltd undertook a comprehensive prospective clinical study with 15 participants (experts in UGRA) and 15 trainees in Portland, United States. The 15 expert participants were all capable of independent clinical practice of UGRA, and therefore met the intended user definition.

Participant Demographics

Expert- All 15 expert participants deliver regular clinical care using UGRA, and 14 of participants are members of relevant professional society (e.g., ASA, ASRA, ESRA, RA-UK), and/or regularly teach UGRA. An impressive majority of participants (n=11, (b) (4) hold advanced further training in UGRA.

Trainee - Seven (n=7, (b) (4)) trainees deliver regular clinical care using UGRA, and 13 of trainees are members of relevant professional society (e.g., ASA, ASRA, ESRA, RA-UK). Unsurprisingly, none of the trainees regularly teach UGRA. A few trainees (n=2, (b) (4) hold an advanced further training in UGRA. Most trainees (n=11, (b) (4)) deliver under (b) (4) blocks annually, with two (n=2, (b) (4) trainees having no experience of any clinical PNB procedures. Most trainees (n=12, (b) (4) do not practice PNB independently. Of the trainees that have carried out PNB procedures, the majority ((b) (4)) stated that they always use ultrasound guidance to perform PNB blocks.

ScanNav Anatomy PNB performance was evaluated in the following manner:

- ScanNav Anatomy PNB performance was assessed by study attendees on 2 models, one of BMI <30 kg/m2, one of BMI =>30kg/m2. Both trainee and expert attendees performed (b) (4) scans with and without the aid of the device, on each model.

- A block evaluation questionnaire was issued to assess device accuracy and safety immediately after using the device in practice. The block evaluation questionnaire was designed to evaluate safety critical structures described in Section 3.16. Ultrasound scans performed during the study were recorded for later analysis.

- Additional benefits were evaluated by assessing the ScanNav Anatomy PNB performance by an intended user supervising another healthcare professional (who is qualified to perform these procedures under supervision). These benefits were assessed using a questionnaire.

- An expert panel independently evaluated ScanNav Anatomy PNB highlighting on the scans recorded from the study. These data were compared to the evaluations made by the attendees during the study.

The study was designed to evaluate the use and benefits of the ScanNav Anatomy PNB device in a simulated clinical environment. The device was used by the study participants to perform several scans on two volunteer models, one with low BMI (<30kg/m2) and one with high BMI (>=30kg/m2), to ascertain the device's performance, safety, benefits, and risks via a questionnaire.

Following the data collection phase, recordings of the scans performed by participants were presented to a panel of three (3) independent experts. The scan data was displayed side-by-side with the corresponding device highlighting. The experts reviewed the entirety of each recorded scan and completed the same questionnaire as participants. The majority panel view of the device's performance and safety profile for each scan was compared to the corresponding view of the expert participant.

The primary endpoint for the study was:

i. Device assists participants in obtaining the correct ultrasound view of the anatomy prior to needle insertion [majority view, at least 8/15 participants in agreement]

The secondary endpoints were:

i. ScanNav Anatomy PNB assists intended users in the identification of anatomical structures in
adult patients, up to BMI 35 kg/m2 [majority view, at least 8/15 participants in agreement].
ii. Device assists participants in supervision and training in anatomical structure identification for
UGRA scanning [majority view, at least 8/15 participants in agreement]
iii. Device improves operator confidence [majority view, at least 8/15 participants in agreement]

Study Results

The predefined primary endpoint was met, and the study data shows that ScanNav Anatomy PNB assisted 63% (19/30) of the study participants to obtain the correct ultrasound view.

All predefined secondary endpoints were also met:

a. ScanNav Anatomy PNB assisted 70% (21/30) of participants to identify the anatomical structures relevant to UGRA.
b. ScanNav Anatomy PNB assisted 87% (13/15) of experts to supervise and train of trainees to identify anatomical structures relevant to UGRA procedures.
c. ScanNav Anatomy PNB improved the confidence of 63% (19/30) of participants while scanning for UGRA.

Pediatric Extrapolation

ScanNav Anatomy Peripheral Nerve Block is indicated for patients age 18 and older. For medical devices, the FD&C Act defines patients before their 22nd birthday as pediatric patients. In this De Novo request, existing clinical data were not leveraged to support the use of the device in a pediatric patient population.

LABELING

ScanNav Anatomy Peripheral Nerve Block labeling consists of Instructions for Use that includes a detailed summary of the clinical evaluation. The Instructions for Use should also include appropriate warnings and cautions associated with potential over reliance on device output in clinical setting.

Intended Users:

Anatomy PNB is intended to be used by or under supervision of an anesthesiologist who is competent to perform UGRA independently:

U.S. board-eligible/board-certified and licensed Medical Doctor meeting the following criteria:

• Completed advanced training (e.g., fellowship) in or hold a qualification related to UGRA

• Regularly delivers direct clinical care using UGRA, including for 'awake' surgery where indicated

• Regularly teach UGRA in the course of their clinical work, including advanced techniques where indicated

Training requirements for users:

Users will not be provided any formal training on the use of the device. However, for the safe and effective use of the device, Anatomy PNB, shall be provided with the instructions for use, product overview video and the QuickStart guide.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of a real-time ultrasound anatomy visualization and labeling device for ultrasound guided regional anesthesia and the measures necessary to mitigate the risks

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

SPECIAL CONTROLS

In combination with the general controls of the FD&C Act, the real-time ultrasound anatomy visualization and labeling device for ultrasound guided regional anesthesia 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.

BENEFIT-RISK DETERMINATION

The risks of the device are based on data collected in a clinical study and human factors study described above.

1. *Adverse events due to inaccurate location identification for nerve blocks (eg., local anesthesia systemic toxicity (LAST), perioperative neurologic syndrome (PONS), Pneumothorax, Peritoneal violation).*

2. *Ineffective nerve blocks due to misinterpretation of anatomical structures by the device.*

3. *Users without specific clinical expertise operating the device*

4. *Ineffective nerve blocks and treatment delay due to corruption in image transfer*

The probable benefits of the device are also based on data collected in a clinical study as described above.

The benefits are subjectively assessed and include:

1. *A 25% response consensus that device assisted or helped expert participants [intended users] when identifying the relevant anatomical structures per block while 5% hindered or made it harder to identify anatomical structures in this cohort.*

2. *A 70% reduction that device use mitigated risk of mistaking an incorrect view as a correct view while it increased the same by* (b) (4)

Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

Benefit/Risk Conclusion

In conclusion, given the available information above, for the following indication statement:

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.

The probable benefits outweigh the probable risks for the ScanNav Anatomy Peripheral Nerve Block. The device provides benefits, and the risks can be mitigated by the use of general controls and the identified special controls.

CONCLUSION

The De Novo request for the ScanNav Anatomy Peripheral Nerve Block is granted and the device is classified as follows:

Product Code: QRG
Device Type: Real-time ultrasound anatomy visualization and labeling device for Ultrasound Guided Regional Anesthesia
Regulation Number: 21 CFR 868.1980
Class: II