August 15, 2025

Smart Alfa Teknoloji San. Ve Tic. A.S.
Utku Kaya
Chief Executive Officer
Universiteler Mah. Ihsan Dogramaci Blv
No:17-1 No.109, Cankaya
Ankara, 06800
Turkey

Re: K250818
Trade/Device Name: Nerveblox
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: July 17, 2025
Received: July 17, 2025

Dear Utku Kaya:

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,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
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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)*
K250818

Device Name
Nerveblox

Indications for Use *(Describe)*
Nerveblox assists qualified healthcare professionals in identifying anatomical structures in the following ultrasound-guided peripheral nerve block regions for use prior to any needle intervention and is used for adult patients 18 years of age or older. It is not used in combination with needles or during needle insertion.

Nerveblox supports users in the following block regions:

- Interscalene Brachial Plexus
- Supraclavicular Brachial Plexus
- Infraclavicular Brachial Plexus
- Cervical Plexus
- Axillary Brachial Plexus
- PECS I & II
- Transversus Abdominis Plane (TAP)
- Rectus Sheath
- Femoral Nerve
- Adductor Canal
- Popliteal Sciatic
- Erector Spinae Plane (ESP)

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.

REVISION TRACKING PAGE

Revision No	Revision Date	Revised By	Revised Chapter / Figure / Table	Content of the Revision
00	-	Cem Volkan DOĞAN	-	First Issue
01	11 July, 2025	Ecem KUSCUOGLU	Summary of Clinical/Non-Clinical Tests edited Summary of Human Factors Testing added Summary of Clinical Testing edited Clearance identification of the ultrasound devices added to the Device Description Summary	Additional information per FDA request

Applicant Details:

Applicant Name: Smart Alfa Teknoloji San. Ve Tic. A.Ş.
Applicant Address: Universiteler Mah. Ihsan Dogramaci Blv. No:17/1-109 Cankaya-ANKARA
Applicant Contact Name: Utku KAYA
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Device Details:

Device Trade Name: Nerveblox
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 #: K232787
Product code: QRG

Device Description Summary:
Nerveblox is a software as a medical device, designed to assist clinicians in identifying anatomy for ultrasound-guided peripheral nerve blocks.

Integrated into commercially available Venue (Venue K240111, Venue Go K240053, Venue Fit K234106 and Venue Sprint K240206) ultrasound systems (GE HealthCare, Chicago, IL), Nerveblox utilizes non-adaptive AI/ML functionalities to highlight anatomical structures by applying color overlays, adding name labels, and providing a quality score that informs the user about the overall image's suitability for anatomical assessment and the completeness level of detected anatomy regarding the key anatomical structures.

While Nerveblox enhances visualization, it does not replace the clinician's expertise but supports anatomical identification prior to the procedure.

Intended use/Indications for Use:
Nerveblox software is intended to assist qualified healthcare professionals in the identification and highlighting of anatomical structures in ultrasound images to support ultrasound-guided regional anesthesia procedures.

Nerveblox assists qualified healthcare professionals in identifying anatomical structures in the following ultrasound-guided peripheral nerve block regions for use prior to any needle intervention and is used for adult patients 18 years of age or older. It is not used in combination with needles or during needle insertion.

Nerveblox supports users in the following anatomical regions:

- Interscalene Brachial Plexus
- Supraclavicular Brachial Plexus
- Infraclavicular Brachial Plexus
- Cervical Plexus
- Axillary Brachial Plexus
- PECS I & II
- Transversus Abdominis Plane (TAP)

- Rectus Sheath
- Femoral Nerve
- Adductor Canal
- Popliteal Sciatic
- Erector Spinae Plane (ESP)

Substantial Equivalence:

Attributes	Predicate Device (K232787)	Subject Device	Comments
Manufacturer	Intelligent Ultrasound Limited	Smart Alfa Teknoloji San. ve Tic. A.Ş.	N/A
Regulation Number	868.1980	868.1980	Same
Regulatory Class	Class II	Class II	Same
Product Code	QRG	QRG	Same
Regulation Name	Real-Time Ultrasound Anatomy Visualization And Labeling Device For Ultrasound Guided Regional Anesthesia	Real-Time Ultrasound Anatomy Visualization And Labeling Device For Ultrasound Guided Regional Anesthesia	Same
Intended use	ScanNav Anatomy Peripheral Nerve Block is intended to assist in the identification and labelling of anatomical structures in live ultrasound images.	Nerveblox software is intended to assist qualified healthcare professionals in the identification and highlighting of anatomical structures in ultrasound images to support ultrasound-guided regional anesthesia procedures.	Same

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.	Nerveblox assists qualified healthcare professionals in identifying anatomical structures in the following ultrasound-guided peripheral nerve block regions for use prior to any needle intervention and is used for adult patients 18 years of age or older. It is not used in combination with needles or during needle insertion.	Same
Intended Use Environment	ScanNav Anatomy Peripheral Nerve Block is intended to be used within a professional healthcare environment where ultrasound scanning, including ultrasound-guided interventional procedures such as regional anesthesia, is conducted.	Nerveblox is intended for use in professional healthcare settings where ultrasound-guided interventional procedures such as regional anesthesia are conducted.	Same
Intended users	ScanNav Anatomy Peripheral Nerve Block is intended to be used by qualified healthcare professionals who have been trained in its use.	Nerveblox is intended for use by qualified healthcare professionals who are licensed to perform ultrasound-guided regional anesthesia procedures and have received training in the use of the software.	Same
Target Population	Patients 18 years of age or older.	Patients 18 years of age or older.	Same

Anatomical Block Regions	10 block regions : • Axillary level brachial plexus • Erector spinae plane • Femoral block • Interscalene level brachial plexus • Popliteal level sciatic nerve • Rectus sheath plane • Supraclavicular level brachial plexus • Sub-sartorial femoral triangle / Adductor canal • Longitudinal suprainguinal fascia iliaca plane • Superior trunk of brachial plexus	12 block regions : • Axillary level brachial plexus • Erector spinae plane • Femoral block • Interscalene level brachial plexus • Popliteal level sciatic nerve • Rectus sheath plane • Supraclavicular level brachial plexus • Adductor canal • Infraclavicular level brachial plexus • PECS I&II • Transverse abdominis plane • Cervical plexus	Predicate device and subject device have some differences for the peripheral nerve block regions supported. The differences are given in the **Table 2** for clarity. These differences, however, do not impact the device's safety or effectiveness, as demonstrated by appropriate verification and validation testing.
Anatomical Structures	• Nerves • Muscles / Tendons • Arteries • Bowel/Peritoneum • Fascial planes • Bone • Transverse process	• Nerves • Muscles / Tendons • Arteries • Peritoneum • Fascial planes • Ribs • Transverse process	Subject device additionally highlights the veins as the key anatomical structure. This difference does not raise different

	• Pleural line / Lung	• Pleura • Veins	questions of safety or effectiveness and has been properly verified and validated in testing.
Device hardware	Touchscreen Panel PC which includes the Anatomy PNB highlighting software	Software integrated into compatible ultrasound systems	The predicate device has its own designated hardware and obtains input ultrasound images via hardware interface while the subject device is a software and runs on clinically available ultrasound systems. This difference does not raise different questions of safety or effectiveness.
Input	Regional anesthesia ultrasound images	Regional anesthesia ultrasound images	Same

Output	Anatomy highlighting	Anatomy highlighting, name labels for anatomical structures and an image quality score.	Both devices highlight the key anatomical structures within the peripheral nerve block regions. However, the subject device also provides a "Quality Score" for the current image to provide additional assistance. This difference does not raise different questions of safety or effectiveness and has been properly verified and validated in testing.
Imaging Modality	Ultrasound	Ultrasound	Same
Image source	Compatible ultrasound systems through a hardware interface (HDMI cable)	Compatible ultrasound systems through a programming interface	Image source is same. The interface to obtain the image is different but

			does not raise questions of safety or effectiveness.
Software device that operates on off-the-shelf hardware	Yes	Yes	Same
Device uses AI/ML algorithms for image anatomy highlighting	Yes	Yes	Same
Algorithm type	Locked deep learning models	Locked deep learning models	Same

Equivalence Discussion

Both the subject device (Nerveblox) and the predicate device (ScanNav Anatomy Peripheral Nerve Block) have the same intended use, which is to assist healthcare professionals in identifying and highlighting anatomical structures in ultrasound images for ultrasound-guided regional anesthesia procedures prior to needling. They also have identical indications for use, except for differences in the specific peripheral nerve block regions supported. These differences, however, do not affect the device's safety or effectiveness, as demonstrated through appropriate verification and validation testing.

Both the subject device and the predicate device utilize convolutional neural networks (CNNs) for their AI algorithms to identify and label anatomical structures on ultrasound images. Although both devices operate in connection with ultrasound images, the method by which they obtain these images differs. While the predicate device captures ultrasound images via an HDMI video output, the subject device is integrated directly into the ultrasound system,

allowing it to acquire images through a programmable interface without requiring an external physical source. ScanNav Anatomy Peripheral Nerve Block functions as an accessory to compatible general-purpose diagnostic ultrasound systems, whereas Nerveblox is software hosted on commercially available compatible ultrasound systems. Another difference in technical characteristics is that, while the predicate device highlights anatomical structures with a colored overlay, the subject device provides both a name label indicating the anatomical structure and a colored overlay on the highlighted area. Additionally, the subject device includes a "Quality Score" for the ultrasound image and distinguishes veins differently from the predicate device. These technological differences, however, do not affect the device's safety or effectiveness, as demonstrated through appropriate verification and validation testing.

Summary of Clinical/Non-Clinical Tests

Based on conducted Clinical/Non-Clinical tests, it is concluded that Nerveblox meets clinical accuracy needs and the overall residual risk of using Nerveblox is low, acceptable and outweighed by the clinical benefits of the device.

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Device Software Functions".

The software verification and validation testing verified that the design requirements were successfully met. The intended use was successfully validated.

Verification/Validation Methods	Acceptance Criteria	Summary of results
Analytical validation	-Anatomical structure detection accuracy is over 0.8. -Dice similarity score is over 0.75. -Quality meter accuracy is over 0.85.	Acceptance criteria were successfully met for all block regions.

Software/cybersecurity tests	Unit test Integration test Software system level test Security requirements test Threat mitigation test Vulnerability test Penetration test	All software/cybersecurity tests have been successfully completed without any anomalies
Clinical safety and accuracy validation	**Anatomical Structures** Accuracy (TP + TN): Correct highlighting of safety critical anatomical structures ≥ 80% FP Rate: Misidentification rate of safety critical anatomical structures < 5% FN Rate: Non-identification rate of safety critical structures < 15% **Image Quality Score** Accuracy of identifying the correct block region > 90% Error Rate of identifying the correct block region < 5% Fair or above agreement with the experts on quality score levels	Accuracy (TP+TN): 97.2% (933 out of 960 scans) Misidentification (FP) Rate: 1.0% (10 out of 960 scans) Non-identification (FN) Rate: 1.8% (17 out of 960 scans) 95.3% 4.7% Weighted Kappa Coefficient (**κ**) ≥ 0.77 Positive Percentage Agreement (PPA) ≥ 61.5 % Negative Percentage Agreement (NPA) ≥ 88.9 %

Summary of Human Factors Testing

Twenty-two (22) U.S.-board certified healthcare professionals licensed to perform Ultrasound-Guided Regional Anesthesia (UGRA) participated in this summative usability validation study conducted in the USA (New York, Houston, and Cleveland), starting on February, 2025. All participants were capable of independent clinical practice of UGRA, and their qualifications aligned with the intended user profile for Nerveblox, as follows:

- U.S. board-certified healthcare professional.
- Licensed to perform regional anesthesia procedures.
- Experienced in ultrasound imaging techniques.
- No color blindness or similar visual limitations.

The study took place in a simulated clinical setting at three locations, including the use of human models simulating patients undergoing UGRA procedures. Human models were selected according to population stratification criteria which may affect usability of the device: BMI <30 kg/m^2 and ≥30 kg/m^2. All study participants completed the essential and critical tasks.

A total of five simulation tasks and seven knowledge tasks were included in this summative human factor study. No use errors were observed during any of the simulation tasks. For four of the five simulation tasks, 19 out of 22 participants completed them without difficulty. Among the seven knowledge tasks, five tasks presented minor difficulties for 1 or 2 participants.

The data obtained during the summative study were analyzed to determine whether any aspect of the final design of the user interface (UI) were implicated or pointed out by test participants as a source of difficulty with use, close call, use error, or task failure. The analysis did not identify 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 Testing

A prospective clinical validation study was conducted to evaluate the performance of Nerveblox, which involved 80 distinct ultrasound scans from 40 healthy volunteers, with ultrasound scans performed by anesthesiologists. The study population included participants with a mean age of 37.9 years, ranging from 18 to 66 years. In terms of body mass index (BMI), 52.5% of participants had a BMI below 30, while 47.5% had a BMI above 30, with a mean BMI of 29.13 (±4.76).

The scans were later processed by the AI, and the results were evaluated by expert U.S. board-certified anesthesiologists. The primary objective was to assess the accuracy of Nerveblox in detecting and highlighting key anatomical structures on ultrasound images. Secondary objectives included evaluating the consistency of the AI's image quality grading against predefined criteria and identifying potential risks in AI-assisted interpretation.

The study measured the software's accuracy in anatomical landmark highlighting by comparing AI-generated results with expert evaluations. The software demonstrated a high accuracy rate of 97%, with a true positive rate of 98% and a true negative rate of 90%. The false-positive rate (FPr) was 10.4%, while false-negative rate (FNr) was 2%. Expert assessments indicated that AI-assisted highlighting reduced the perceived risk of adverse events in 61.67% of cases and reduced the risk of block failure in 66.36%. The AI also contributed to procedural efficiency while maintaining safety concerning risks such as pneumothorax, local anesthetic systemic toxicity, peritoneum violation, and nerve injury.

The image quality scores generated by the Nerveblox software were compared against expert evaluations for each scan using Positive Percent Agreement (PPA), Negative Percent Agreement (NPA) across 5 quality levels, and the weighted Kappa coefficient. Substantial agreement was observed across all block regions. PPA ranged from 61.5 % to 100.0 % and NPA from 88.9 % to 100.0 % across individual score levels and regions. Weighted Kappa values ranged from 0.77 to 0.98 across all block regions, indicating substantial agreement with expert assessments.

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.