Tissue Differentiation Intelligence, LLC
℅ Lorry Huffman
Principal Consultant, Regulatory Affairs
Qserve Group, US, Inc.
303 Twin Dolphin, Suite 600
REDWOOD SHORES CA 94065

March 12, 2020

Re: K192388
Trade/Device Name: SonoVision™ Ultrasound Imaging System
with Beluga1™ Ultrasound Probe
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: February 5, 2020
Received: February 7, 2020

Dear Lorry Huffman:

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 (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 located 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.

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 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 Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192388

Device Name

SonoVision™ Ultrasound Imaging System with Beluga1™ Ultrasound Probe

Indications for Use *(Describe)*

The SonoVision™ Ultrasound Imaging System is a general purpose ultrasound system intended for use by a qualified physician for the visualization and evaluation of nerves, vascular and other anatomical structures. The system provides imaging assistance in spinal procedure applications.

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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Section 5: 510(k) Summary – [21 CFR 807.92]

K192388

807.92(a)(1), (2), (3)

Date Prepared: March 6, 2020

Submitter's Name: Tissue Differentiation Intelligence, LLC
Christian Zaal, Vice President Operations
234 NE 4th Avenue
Delray Beach, FL 33486
+1-305-351-2011

Device Trade Name: SonoVision™ Ultrasound System with Beluga1™ Ultrasound Probe

Common Name: Ultrasound pulsed doppler imaging system

Review Panel: OIR

Classification Name: Ultrasound pulsed doppler imaging system: 892.1550

Classification Code: IYN: Ultrasound pulsed doppler imaging system

IYO: Ultrasonic pulsed echo imaging system

ITX: Diagnostic ultrasonic transducer

Predicate Device(s):

	Primary Predicate	**Reference Predicate**
	Accuro™ 3000 Ultrasound System	Esaote 6200 and 6250 Ultrasound System
510(k) Number	K132736	K153277
Classification Code	IYO, ITX	IYN, IYO, ITX
Regulation	892.1550	892.1550

Device Description *807.92(a)(4)***:**

The SonoVision™ Ultrasound Imaging System with Beluga1™ transducer probe is a general purpose, Track 1, ultrasound system intended for use by a qualified physician for the visualization and evaluation of nerves, vascular and other anatomical structures. The Beluga1™ is an ultrasound imaging probe that has been ergonomically designed for use in intraoperative procedures.

The system is comprised of the SonoVision™ console & monitor, 10 MHz transducer imaging probe (Beluga1™), and control software. The system includes image processing software that can be used to define anatomical features in an ultrasound B-mode image. The Beluga1™ Imaging Probe has been developed for specific application in spine procedures.

Intended Use *807.92(a)(5)***:**

The SonoVision™ Ultrasound Imaging System is a general purpose ultrasound system intended for use by a qualified physician for the visualization and evaluation of nerves, vascular and other anatomical structures. The system provides imaging assistance in spinal procedure applications.

Technological Characteristics *807.92(a)(6)***:**

The SonoVision™ Ultrasound Imaging System has the same fundamental technological characteristics as the primary and reference predicates. Similar features are as follows:

- Intraoperative clinical use
- Spine application
- B-mode imaging
- Doppler (echographic image)/color flow mapping
- Real-time 2-D bone and tissue scanning (differentiation)
- Radiofrequency (RF) energy for its internal function resulting in very low RF emissions
- Non-user adjustable acoustic output
- Proprietary software performance
- Data capture and external storage
- Electrical safety/EMC/acoustic output meets standards
- Reusable probe

Summary of Non-Clinical Test - Performance and Safety Testing *807.92(b)(1)*

The SonoVision™ Ultrasound Imaging System was evaluated for performance, acoustic output, biocompatibility, cleaning and sterilization as well as thermal, electrical, electromagnetic, and mechanical safety, and found to conform with the following FDA recognized standards:

- IEC 60601-1-2: 4th edition (19-8) *Medical Electrical Equipment - Part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic disturbances - requirements and tests*
- IEC 60601-1-1: 2005/(R)2012 And A1:2012 (19-4) *Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: general requirements [including: corrigendum 1 (2011)]*

<u>Acoustic output</u>

- IEC 60601-2-37 ED 2.1 2015 medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- IEC 62359 Ed 2.1 2017-09 Ultrasonics - field characterization - test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields [Including: technical corrigendum 1 (2011)]
- NEMA UD 2 revision 3 2009 Acoustic output measurement standard for diagnostic ultrasound equipment

<u>Temperature rise of the device is in accordance with</u>:

- IEC 60601-2-37 ED 2.1 2015 medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

Biocompatibility

ISO 10993-1 5th edition 2018-08 for limited exposure, external communicating device. ISO 10993-1 Annex A Table A.1 – *Evaluation tests for consideration* indicate biological effects cytotoxicity, sensitization, irritation or intracutaneous reactivity be evaluated for the medical device category of the transducer.

Sterilization

ISO 14937:2009 *Sterilization of healthcare products-General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*.

Summary of Clinical Tests *807.92(b)(1)*

In vivo testing was conducted to demonstrate performance of the device in human applications.

Conclusion *807.92(b)(1)***:**

SonoVision™ Ultrasound Imaging System with Beluga1™ transducer probe and the Accuro™ 3000 Ultrasound System both provide general purpose ultrasound tissue imaging, ability to highlight and enhance bone anatomy and state of the art features such as reusable probe, touchscreen operation, and data capture and external storage. Doppler imaging and intraoperative features are supported by the reference predicate Esaote 6000/6250.

The predicate comparison table and performance and safety testing provided in this 510(k) is sufficient to demonstrate that SonoVision™ Ultrasound Imaging System with Beluga1™ transducer probe is substantially equivalent to preamendment devices, Accuro™ 3000 ultrasound system, and Esaote 6000/6250 Ultrasound System and meets requirements for Track 1 as described in FDA Final Guidance *Marketing Clearance of Diagnostic Ultrasound Systems and Transducers-June 27, 2019*.