July 1, 2024

Interson Corporation
Vamsi Vangipuram
Quality/Regulatory Affairs Manager
7150 Koll Center Parkway
Pleasanton, California 94566

Re: K233734
Trade/Device Name: Interson USB Ultrasound Probe System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX

Dear Vamsi Vangipuram:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change for your device cleared on December 22, 2023. Specifically, FDA is updating this SE Letter because FDA inadvertently indicated that the SE determination also included review and clearance of a predetermined change control plan (PCCP). However, your 510(k) submission did not include a PCCP, so FDA is providing this administrative correction. Please see the attached revised clearance letter.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Yanna Kang, OHT8: Office of Radiological Health, (301)796-6704, Yanna.Kang@fda.hhs.gov.

Sincerely,

Yanna S. Kang -S

Yanna Kang, Ph.D.
Assistant Director
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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Interson Corporation
Vamsi Vangipuram
Quality/Regulatory Affairs Manager
7150 Koll Center Parkway
Pleasanton, California 94566

Re: K233734
Trade/Device Name: Interson USB Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: November 21, 2023
Received: November 22, 2023

Dear Vamsi Vangipuram:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change for your device cleared on December 22, 2023.

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,

Yanna S. Kang -S

Yanna Kang, Ph.D.
Assistant Director
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233734

Device Name
Interson USB Ultrasound System

Indications for Use *(Describe)*
The Interson USB Ultrasound System is intended for diagnostic ultrasound imaging in B, color Doppler, M mode or Combined (B+ Color) modes. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications:

Fetal/Obstetric
Abdominal
Pediatric
Small Organ
Trans-Rectal
Trans-Vaginal
Musculo-skeletal (conventional)
Musculo-skeletal (superficial)
Urology
Gynecology
Pelvic Floor
Neuro-muscular
Cardiac
Peripheral Vessel

The system is intended for use by trained healthcare professionals having a general knowledge of the use of ultrasound imaging devices and imaging protocols in environments where healthcare is provided by healthcare professionals.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K233734 510(k) Summary

In accordance with 21CFR 807.92 the following summary of information is provided.

Submitter Information

Date of submission:	11/21/2023
Submitter information:	Interson Corporation 7150 Koll Center Parkway Pleasanton, CA 94566
Establishment Registration No:	2939830
Contact person:	Vamsi Vangipuram Quality/Regulatory Manager (925) 462-4948 (tel) (925) 462-4833 (fax) vvangipuram@interson.com

Name of Device and Classification

Device trade name:	Interson USB Ultrasound System
Common name:	Diagnostic ultrasound system and transducers
Classification:	Class II

21 CFR Section	Classification Name	Product Code
892.1550	Ultrasonic pulsed doppler imaging system	IYN
892.1560	Ultrasonic pulsed echo imaging system	IYO
892.1570	Diagnostic ultrasonic transducer	ITX

Predicate Device

Interson USB Ultrasound Probe System	K163443	4/13/2017

Hereinafter, the Subject Device is called as “Interson USB Ultrasound System (Proposed)” in this submission because the predicate device has the same trade name.

Device Description

The Interson USB Ultrasound Imaging System (Proposed) is a self-contained portable, solid-state, multiple-mode and multiple-application ultrasound imaging system. The system comprises a series of handheld probes containing an ultrasound generator/receiver, analog to digital converter, microcontroller, control logic, USB 2.0 interface, and software-based controls offering a full complement of conventional operating modes, parameter controls, and recording functions.
The system operates in B, color Doppler, M mode and combined B + color Doppler modes. The selection of transducers offered with the system permits a wide range of clinical applications including Abdominal, Fetal, Pediatric, Musculoskeletal, Cardiac, Small organ, Neuro-muscular, Urology, OB/Gyn and Peripheral vessel.

Intended Use/Indications for Use

The Interson USB Ultrasound System is intended for diagnostic ultrasound imaging in B mode, M mode, Color Doppler or Combined (B+ Color) modes. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications:

Fetal/Obstetric
Abdominal
Pediatric
Small Organ
Trans-Rectal
Trans-Vaginal
Musculo-skeletal (conventional)
Musculo-skeletal (superficial)
Urology
Gynecology
Pelvic Floor
Neuro-muscular
Cardiac
Peripheral Vessel

The system is intended for use by trained healthcare professionals having a general knowledge of the use of ultrasound imaging devices and imaging protocols in environments where healthcare is provided by healthcare professionals.

Determination of Substantial Equivalence

The subject device is a modification of the Interson USB Ultrasound System that has FDA 510(k) clearance under K163443. The proposed modification is to add the cardiac indication to the Ultrasound system with the indicated probe.

Technological Comparison

This labeling modification does not impact the technological features of the device. The subject device has the same technological characteristics as the predicate device as a general-purpose ultrasound imaging system.

Interson Corporation considers the Interson USB Ultrasound System to be safe, effective and performance is substantially equivalent to the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

Given the cardiac indication added to the labeling and no other changes to the device, non-clinical testing and clinical testing are not required. Interson Corporation considers the Interson USB Ultrasound System to be as safe, effective and performance is substantially equivalent to the predicate device.