DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 13, 2017

Interson Corporation
% David Asarnow, Ph.D.
Quality/Regulatory Manager
7150 Koll Center Parkway
PLEASANTON CA 94566

Re: K163443
Trade/Device Name: Interson USB Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: March 17, 2017
Received: March 17, 2017

Dear Dr. Asarnow:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K163443

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, 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
Musculo-skeletal (conventional)
Musculo-skeletal (superficial)
Urology
Gynecology
Pelvic Floor
Neuro-muscular
Peripheral Vessel

The system is intended for use 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.

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## SECTION 1.3 - INDICATIONS FOR USE

The Interson USB Ultrasound System is intended for diagnostic ultrasound imaging in B, 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
Musculo-skeletal (conventional)
Musculo-skeletal (superficial)
Urology
Gynecology
Pelvic Floor
Neuro-muscular
Peripheral Vessel

The system is intended for use by healthcare professionals.

The Indications for Use statement on Form 3881 is provided in Tab 4, followed by the clinical applications and modes of operation applicable to each application for each transducer and for the system.

Diagnostic Ultrasound Indications for Use

Interson USB Ultrasound System
**Device Name: GP-C01 Transducer**
Mode: B, color Doppler, B + color Doppler
Intended Use: Diagnostic ultrasound imaging and fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **General (Track 1 only)** | **Specific (Tracks 1&3)** | **B** | **M** | **PWD** | **CWD** | **Color Doppler (CD)** | **Combined (B+CD)** | **Other* (Specify)** |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal/Obstetric | **N** | | | | **N** | **N** | |
| | Abdominal | **N** | | | | **N** | **N** | |
| | Intra-Operative (Specify) | | | | | | | |
| | Intra-Operative Neurological | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric (excluding transcranial & neonatal) | | | | | | | |
| | Small Organ (Scrotum, prostate, lymph nodes, thyroid, breast) | **N** | | | | **N** | **N** | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-card.) | | | | | | | |
| | Muscular-Skeletal (Conventional) | **N** | | | | **N** | **N** | |
| | Muscular-Skeletal (Superficial) | **N** | | | | **N** | **N** | |
| | Intravascular | | | | | | | |
| | Other (Urology) | **N** | | | | **N** | **N** | |
| | Other (Gynecology) | **N** | | | | **N** | **N** | |
| | Other (Pelvic Floor) | **N** | | | | **N** | **N** | |
| | Other (Neuromuscular) | **N** | | | | **N** | **N** | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Intravascular (Cardiac) | | | | | | | |
| | Trans-esoph. (Cardiac) | | | | | | | |
| | Intra-cardiac | | | | | | | |
| | Other (Specify) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (Specify) | | | | | | | |

N = New Indication, P=Previously cleared by FDA; E=added under this appendix
*Examples of other modes may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler and Color Velocity Imaging

Diagnostic Ultrasound Indications for Use

Interson USB Ultrasound System
**Device Name: SP-L01 Transducer**
Modes: B, color Doppler, B + color Doppler
Intended Use: Diagnostic ultrasound imaging and fluid flow analysis of the human body as follows:

| **Clinical Application** | | **Mode of Operation** | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **General (Track 1 only)** | **Specific (Tracks 1&3)** | **B** | **M** | **PWD** | **CWD** | **Color Doppler (CD)** | **Combined (B+CD)** | **Other* (Specify)** |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal/Obstetric | | | | | | | |
| | Abdominal | **N** | | | | **N** | **N** | |
| | Intra-Operative (Specify) | | | | | | | |
| | Intra-Operative Neurological | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric (excluding transcranial & neonatal) | **N** | | | | **N** | **N** | |
| | Small Organ (Scrotum, prostate, lymph nodes, thyroid, breast) | **N** | | | | **N** | **N** | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-card.) | | | | | | | |
| | Muscular-Skeletal (Conventional) | **N** | | | | **N** | **N** | |
| | Muscular-Skeletal (Superficial) | **N** | | | | **N** | **N** | |
| | Intravascular | | | | | | | |
| | Other (Urology) | **N** | | | | **N** | **N** | |
| | Other (Gynecology) | **N** | | | | **N** | **N** | |
| | Other (Pelvic Floor) | **N** | | | | **N** | **N** | |
| | Other (Neuromuscular) | **N** | | | | **N** | **N** | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Intravascular (Cardiac) | | | | | | | |
| | Trans-esoph. (Cardiac) | | | | | | | |
| | Intra-cardiac | | | | | | | |
| | Other (Specify) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | **N** | | | | **N** | **N** | |
| | Other (Specifiy) | | | | | | | |

N = New Indication, P=Previously cleared by FDA; E=added under this appendix
*Examples of other modes may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler and Color Velocity Imaging

Diagnostic Ultrasound Indications for Use

**Device Name: Interson USB Ultrasound System**

Modes: B, color Doppler, B + color Doppler
Intended Use: Diagnostic ultrasound imaging and fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **General (Track 1 only)** | **Specific (Tracks 1&3)** | **B** | **M** | **PWD** | **CWD** | **Color Doppler (CD)** | **Combined (B+CD)** | **Other* (Specify)** |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal/Obstetric | N | | | | N | N | |
| | Abdominal | **N** | | | | **N** | **N** | |
| | Intra-Operative (Specify) | | | | | | | |
| | Intra-Operative Neurological | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric (excluding transcranial & neonatal) | **N** | | | | **N** | **N** | |
| | Small Organ (Scrotum, prostate, lymph nodes, thyroid, breast) | **N** | | | | **N** | **N** | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-card.) | | | | | | | |
| | Muscular-Skeletal (Conventional) | **N** | | | | **N** | **N** | |
| | Muscular-Skeletal (Superficial) | **N** | | | | **N** | **N** | |
| | Intravascular | | | | | | | |
| | Other (Urology) | **N** | | | | **N** | **N** | |
| | Other (Gynecology) | **N** | | | | **N** | **N** | |
| | Other (Pelvic Floor) | **N** | | | | **N** | **N** | |
| | Other (Neuromuscular) | **N** | | | | **N** | **N** | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Intravascular (Cardiac) | | | | | | | |
| | Trans-esoph. (Cardiac) | | | | | | | |
| | Intra-cardiac | | | | | | | |
| | Other (Specify) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | **N** | | | | **N** | **N** | |
| | Other (Specifiy) | | | | | | | |

N = New Indication, P=Previously cleared by FDA; E=added under this appendix
*Examples of other modes may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler and Color Velocity Imaging

**510(k) Summary K163443**

Provided in accordance with 21CFR 807.92 (c).

**Submitter Information- 21 CFR 807.92 (a)(1)**

| | |
|---|---|
| Date of submission: | 11/28/2016 |
| Submitter information: | Interson Corporation<br>7150 Koll Center Parkway<br>Pleasanton, CA 94566 |
| Establishment Registration No: | 2939830 |
| Contact person: | David Asarnow<br>Quality/Regulatory Manager<br>(925) 462-4948 (tel)<br>(925) 462-4833 (fax)<br>dasarnow@interson.com |

**Name of Device and Classification – 21 CFR 807.92 (a)(2)**

| | |
|---|---|
| Device trade name: | 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 |

**Track**

Track 3

**Predicate Device – 21 CFR 807.92 (a)(3)**

| | | |
|---|---|---|
| Philips Lumify Diagnostic Ultrasound System | K152899 | 10/30/2015 |
| Interson USB Ultrasound Probe System | K070907 | 4/17/2007 |

**Device Description – 21 CFR 807.92 (a)(4)**:

The Interson USB Ultrasound Imaging System 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 selection of transducers offered with the system permit a wide range of clinical applications including Fetal/Obstetric, Abdominal, Pediatric, Small Organ, Musculo-skeletal, Urology, Gynecology, Pelvic Floor, Neuro-muscular, and Peripheral Vessel.

The initial operational settings for each transducer are preprogrammed in the system. User-customized parameter settings for each transducer may be set by the operator and stored for recall as needed via the system control panel. Customization includes transmit power, images controls selection, and Time Gain Compensation (TGC). Controls are also provided to select display format and to utilize the Cine function.

The Interson USB Ultrasound transducers operate in B-Mode, color Doppler, and combined mode (B + color Doppler), providing high resolution and high penetration performance. The product family uses curved and flat linear array transducers and includes a General Purpose (GP) probe and a Small Parts (SP) probe.

The SeeMore software application used in the Interson USB Ultrasound System supports static image acquisition and a cine function capable of storing up to 32 to 1024 sequential images. Management of patient history is enabled by the image or cine-storage function.

The SeeMore control software runs on standard Microsoft Windows platforms.

**Intended Use/Indications for Use – 21 CFR 807.92 (a)(5)**

The Interson Ultrasound Imaging System is intended for diagnostic ultrasound imaging in B, 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
Musculo-skeletal
Urology
Gynecology
Pelvic Floor
Neuro-muscular
Peripheral Vessel

The system is intended for use by healthcare professionals.

**Product Models**

| Model | Common Applications |
|---|---|
| Transducer Model GP- C01 | Fetal/Obstetric, Abdominal, Urology, Musculo-skeletal, Small Organs, Neuromuscular |
| Transducer Model SP-L01 | Pediatric, Small Organs, Peripheral Vessel |

All models are used with SeeMore control software.

**Summary of technological characteristics of the device compared to the predicate device- 21 CFR 807.92 (a)(6)**

| Device Features | Subject Device: Interson Ultrasound System | Predicate 1: Philips Lumify K152899 | Predicate 2: Interson Ultrasound System K070907 |
|---|---|---|---|
| Intended Use | Diagnostic ultrasound imaging in B, color Doppler and Combined (B + Color) modes. | Diagnostic ultrasound imaging in B, color Doppler, and Combined (B + Color) modes. | Diagnostic ultrasound imaging in B mode (all transducers), A mode (ophthalmic) |
| Indications for Use | Indicated for diagnostic ultrasound imaging and fluid flow analysis in specified applications | Indicated for diagnostic ultrasound imaging and fluid flow analysis in specified applications | Indicated for diagnostic ultrasound imaging in specified applications |
| Array Geometry | Curved and linear | Curved and linear | Non-Array |
| Mechanics | Solid State | Solid State | Mechanical |
| Software platform | Commercial off-the-shelf operating system (Windows) | Commercial off-the-shelf operating system (Android) | Commercial off-the-shelf operating system (Windows) |
| Software control | Standalone | Standalone | Standalone |
| Measurement function | 2D measurement and area measurement | 2D measurement tool | 2D measurement tool |
| Wireless networking | Not supported | Supported | Not supported |
| Connector | USB | USB | USB |

**Determination of Substantial Equivalence**

Non-clinical Performance Data

Non-clinical testing relied on in this premarket notification submission for a determination of substantial equivalence include tests which show compliance with the following standards:

1. Recognition Number 12-105: NEMA UD 2-2004 (R2009), Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3. (Radiology)

2. Recognition Number 19-4: AAMI ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)

3. Recognition Number 12-293: IEC 60601-2-37 (2015), Amendment 2, Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment. (Radiology) 4. Recognition Number 19-8: IEC 60601-1-2 Edition 4.0 2014-02, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

5. Recognition Number 5-89: IEC 60601-1-6 Edition 3.1 2013-10, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

6. Recognition Number 5-40: ISO 14971 Second edition 2007-03-01, Medical devices - Application of risk management to medical devices 7. Recognition Number 2-173: AAMI ANSI ISO 10993-10:2010/(R)2014, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

8. Recognition Number 2-153: AAMI ANSI ISO 10993-5:2009/(R)2014, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

Summary of Clinical Tests

The Interson USB Ultrasound System product family introduces no new modes, features, or technologies relative to the predicate devices (Philips Lumify K152899 and Interson K070907) that require clinical testing. The clinical safety and effectiveness of ultrasound systems with these characteristics are well accepted for both predicate and subject devices.

514 Performance Standards

There are no Sec. 514 performance standards for this device.

Prescription Status

This is a prescription device. The prescription device statement appears in the labeling.

Sterilization Site(s)

Not applicable. No components are supplied sterile.

Conclusions

Interson Corporation concludes that the subject device, the Interson Ultrasound USB Imaging System, has been shown to be substantially equivalent to the predicate devices identified above.