# 510(k) Summary
# 807.92(c)

**Sponsor** **807.92(a)(1)**

| | |
|---|---|
| Company Name: | US Vascular, LLC |
| Company Address: | 4970 SW Menlo Drive<br>Beaverton, OR 97005 |
| Telephone: | 800-326-1169 |
| Contact Person: | Galen Spooner |
| Summary Preparation Date: | June 20, 2013 |

SEP 27 2013

**Device Name:** **807.92(a)(2)**

| | |
|---|---|
| Trade Name: | VascuLab VL40xx, VL4000, VL4010, VL4030 |
| Common/Usual Name: | CW Doppler, PPG, VPR / PVR |
| Classification Name: | Transducer, Ultrasonic |
| Regulation Number: | 21 CFR 870.2880 |
| Product Code: | JOP |
| Device Classification: | Class II |

**Predicate Device** **807.92(a)(3)**

| 510k Number | Product | Company |
|---|---|---|
| Viasonix, LTD | Falcon/Pro, Falcon/Quad and Falcon/ABI+ | K111416 |

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

The VL40xx is a family of products designed for non-invasive peripheral vascular diagnostic systems. The VL40 indicates the family of products that are all made from the same parts with the only differences being that some parts are not installed or some features are not enabled. The "xx" will be used to indicate the family of products. Options of what Doppler or PPG probes are installed do not qualify for a specific model number because there is no physical change to the device to add them. Different air channels require a model number because the valves require a physical change to the device that can only be done at the factory. Specifically the following models are used.

- Model 4000: full system, twelve channel air
- Model 4010: full system, two channel air portable
- Model 4030: ABI (Ankle Brachial Index), six channel air

The base unit has the same main printed circuit board (PCB), battery, speaker, software, and power supply.

Adding the PPG option requires installing a PCB module to the main PCB and attaching the PPG sensors to the outside of the case.

Adding the Doppler requires attaching the desired frequency probe (4 or 8 MHz) to the case. All Doppler frequency probes use the same PCB logic. This means that any probe frequency can be added without any changes to the main PCB or the connectors. The universal Doppler probe is possible because all the Doppler electronics are in the probe. The device PCB for the Doppler only has the logic to turn on the probe and read the data. The Doppler probe has all the electronics to control the IQ signal separation and power output of the probe.

Adding the temperature reading requires purchasing a cleared FDA IR temperature probe from a 3rd party (example Exergen model TAT 5000, K011291). The IR device is a complete standalone product with its own FDA clearance. The VL40xx simply provides a method in software for the operator to record the temperature samples in a table for convenience of reporting. The temperature tests protocols do not care about the absolute temperature readings but do care about the differential readings. What is important is the temperature difference of before and after readings.

For the above features there are no changes to the case and the changes can be made at any time.

The following features require changes to the back panel of the case to support the number of air hoses. The number of air hoses installed is 2, 6, or 12. Internally only the required valves, pressure sensors, and pumps will be installed. Adding air hoses later would require a new case and the appropriate valves, pressure sensors, and pumps to be added. It is much easier to install all the valves and manage the air connectors by choosing what air hoses are attached externally. Unless weight / portability are an issue the easiest solution will always be to choose the 12 air hose system and manage the external air hoses. The external air hoses can be changed at any time to create a system that has 2-12 air hoses as needed. The VL4000 is the model with all air hoses enabled internally.

The air hoses are color coded to help the user attach them to the correct blood pressure cuff. Each air hose has a Red for Right and Lemon for Left code in addition to another color (white, black. orange, yellow, blue, and green) to help identify the location of the cuff. The software always displays the color of the side (Red or Lemon) and the color of the location that it intends to use. The system has no way to determine that the user connects the air hose to the correct cuff at the correct location.

The software for all models is exactly the same. The software automatically detects what features are installed. All models have the following software features: patient details, patient history, comments, storage, printing, print preview, configuration, and online help. Optional software features include Modality Work List (MWL), exporting of data using DICOM Images / Structured Reporting, email, native PDF, long term data storage, data mirroring, and online support.

The VL4030 ABI system will have all tests disabled in software except for the ABI specific tests.

One of the main measurements of the system is segmental systolic blood pressures. In general, the measurement is conducted by applying an appropriately sized cuff to the measured segment, obtaining

a reference PPG or a Doppler signal in a location distal to the cuff placement, and then inflating the cuff to such a pressure that will occlude the blood vessels and prevent blood flow distal to the cuff location, which will result in disappearance of the reference signal. Then, a slow cuff deflation begins, and the instantaneous cuff pressure at which the reference signal reappears is typically defined as the segmental systolic blood pressure. While the software automatically places a cursor at the time location which is suspected as being the systolic pressure, it is the total responsibility of the system operator and the medical staff to modify the cursor location according to their medical training, and define the correct segmental pressure.

Based on the segmental pressures, the pressure indices are calculated, as the ratio between the systolic segmental pressure, and the higher of the 2 brachial systolic pressures that does not exceed a non-compressible limit (usually 240 mmHg). The ABI index is a commonly used index, which is a specific case of the above, calculated as the systolic right or left ankle pressure, divided by the higher of the right or left brachial systolic pressure.

The other main measurement of the system is recording a wave that represents the flow of blood for each heartbeat. The three main modalities for this are the Doppler, PPG, and PVR wave forms. All three of these modalities produce a wave form that has a systolic up stroke, a diastolic down stroke, a pause, and a repeat. Researchers have shown that the shape of these waveforms is a great indicator of disease and that the actual measurement of the wave is not as important.

The system has a wireless remote control. Everything that the remote can do can also be done with the keyboard. The advantage of the remote is that it provides the most common functions needed to perform the measurement without requiring the operator to reach for the keyboard.

If the IR remote is not available then the user will access the VL40xx using a directly wired keyboard, mouse, or touchscreen.

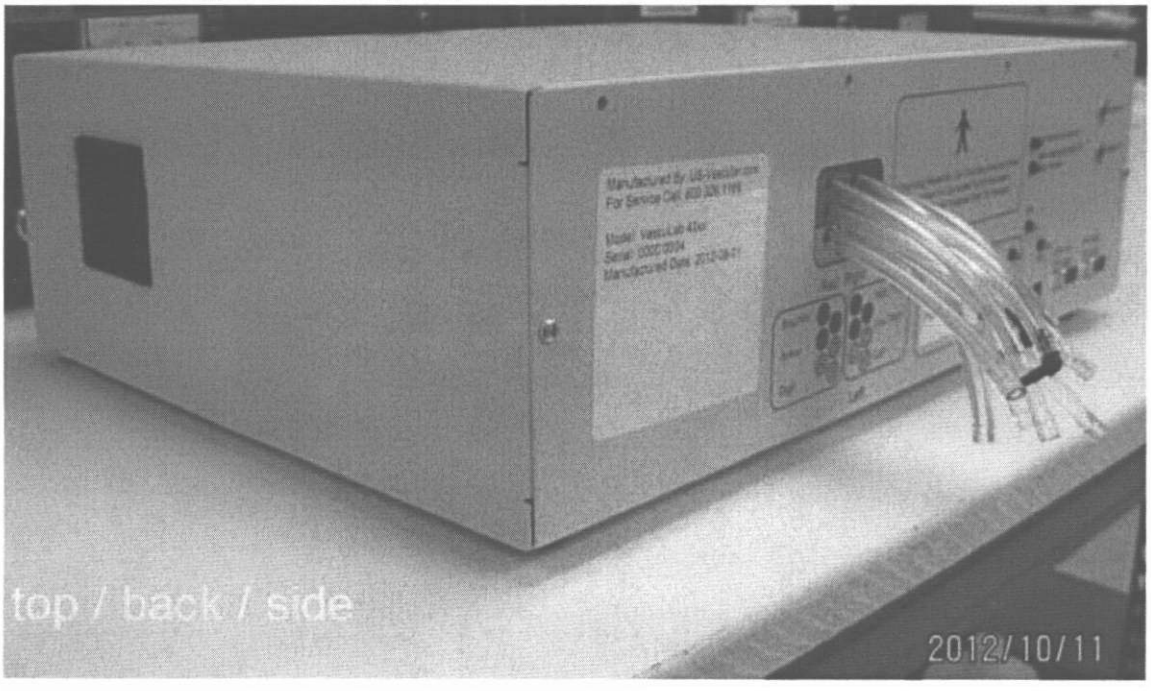
The scientific principal of CW Doppler in very high level terms is as follows. A crystal is cut in half. One half of the crystal has a 4 or 8 MHz sine wave applied. When the acoustic output of the crystal is focused into human tissue it will bounce back and be absorbed by the remaining crystal. Any Doppler effect caused by moving blood can be detected in the phase shift when the transmitted signal is compared with the echoed signal. The phase shift for blood in humans is usually less than 6 kHz and therefore makes for a nice audio signal that can easily be heard. Most modern CW Doppler systems will use IQ modulation and FFT to detect the spectral of the audio signal returned. Tracing the envelope of the spectral will provide the familiar heart beat trace. The CW Doppler can measure the velocity of blood in a specific artery.

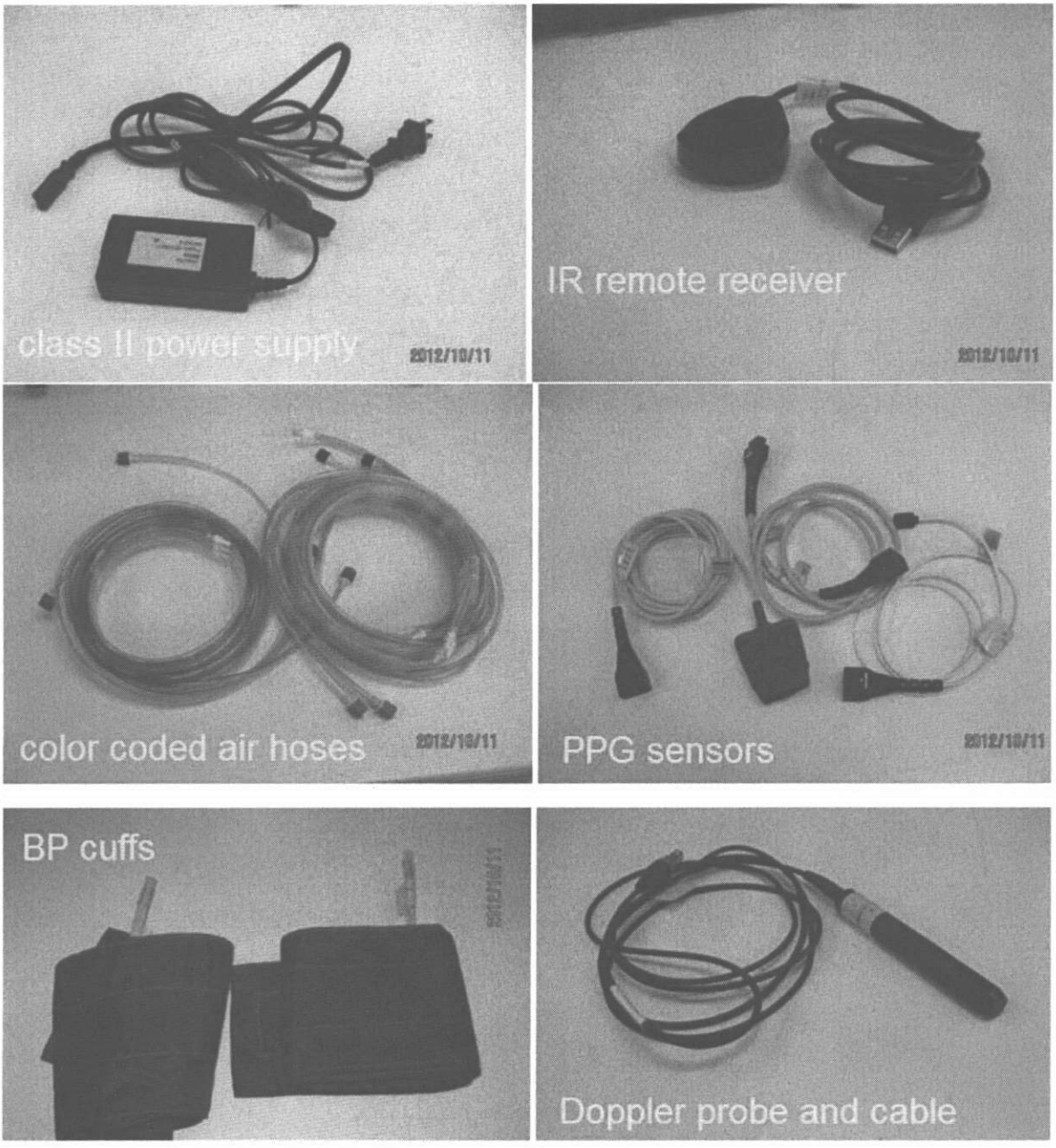
The scientific principal of PPG in very high level terms is as follows. An Infra-Red pulse is provided by an LED and applied to the skin. The blood and tissue will absorb and reflect the IR signal. The amount of blood in the capillaries will determine how much IR signal is absorbed or reflected. An LED sensor is applied that measures the reflected IR signal. Displaying the LED sensor output will provide the familiar heart beat trace. The PPG can measure the change in blood flow in the skin.

The scientific principal of VPR in very high level terms is as follows. A cuff is placed around an arm or leg and inflated to 60 mmHg. The higher the pressure without occluding the blood flow (below systolic blood pressure) will produce the best pressure change in the cuff for each heartbeat. Each heartbeat will cause a pressure change in the cuff ranging from 0.01 – 0.5 mmHg. Displaying the pressure sensor output will provide the familiar heart beat trace. The VPR can measure the change in blood flow for a network of arteries.

The speaker is located on the front of the VL40xx and all other connectors (Doppler, PPG, VPR, USB, power supply, and status LEDs) are on the back.


top / front / side / speaker
2012/10/11


top / back / side
2012/10/11




**Indications for Use** **807.92(a)(5)**

The VL40xx is a Non-Invasive diagnostic system designed to detect peripheral vascular pathology in adults. In all cases the intended use is for spot checking and attended use by trained medical professionals in a hospital or medical facility by the order of a medical doctor.

The VL40xx is not intended to replace other means of evaluating vital patient physiological processes, is not intended to be used in fetal applications, and is not intended to be used inside the sterile field.

**Comparison of Technical Characteristics** **807.92(a)(6)**

| Feature | Falcon Pro, Quad, ABI+ | VL40xx VL4000, VL4010, VL4030 | Diff |
|---|---|---|---|
| 510(k) number | K111416 | this 510(k) | |
| classification | JOP | JOP | |
| date | 2011-11-15 | pending | |
| manufacture | Viasonix | US Vascular | |
| Indications for Use | intended for use in the noninvasive evaluation of peripheral vascular pathology in patients.<br>The devices are not intended to replace other means of evaluating vital patient physiological processes, are not intended to be used in fetal applications, and are not intended to be used inside the sterile field.<br>They are to be used by trained medical personnel in hospitals, clinics and physician's offices by prescription or doctor's orders. | A Non-Invasive diagnostic system designed to detect peripheral vascular pathology in adults. In all cases the intended use is for spot checking and attended use by trained medical professionals in a hospital or medical facility by the order of a medical doctor.<br>The VL40xx is not intended to replace other means of evaluating vital patient physiological processes, is not intended to be used in fetal applications, and is not intended to be used inside the sterile field. | |
| battery powered | no | yes | 1 |
| auto cuff inflation | yes | yes | |
| pressure channels | 4, 10 | 2, 6, 12 | 2 |
| PVR sensors | 4, 10 | 2 | 2 |
| PPG sensors | 4, 5 | 2 | 2 |
| CW Doppler probes | 4, 8, 10 MHz | 4, 8 MHz | 3 |
| acoustic testing | track 1 | track 1 | |
| Max Ispta.3 4 MHz | 691 mW/cm$^2$ | 177 mW/cm$^2$ | 4 |
| Max Ispta.3 8 MHz | 662 mW/cm$^2$ | 249 mW/cm$^2$ | 4 |
| Doppler volume control | yes | yes | |
| Doppler spectral | 256 FFT | 256 FFT | |
| Directional Doppler invert | yes | yes | |
| Doppler envelope | yes | yes | |

| Feature | Falcon Pro, Quad, ABI+ | VL40xx VL4000, VL4010, VL4030 | Diff |
|---|---|---|---|
| Temperature Measurement | Yes, auto | Yes, manual | |
| remote control | yes | yes | |
| touch screen | yes | yes | |
| mouse & keyboard | yes | yes | |
| printer | yes | yes | |
| strip chart | no | no | |
| DICOM/SR | yes | yes | |
| patient storage | yes | yes | |
| Doppler, PVR, segmental pressure, exercise, reflux, Raynauds | yes | yes | |
| Standards tested to | EN-60601-1 (1990)<br><br><br>IEC-60601-1-2 (Ed3:2007)<br>IEC-60601-2-37 (2007)<br>IEC-62304 (2006)<br>ISO 14971 (2007) | EN-60601-1 (1990)<br>IEC-60601-1 (Ed2:1998)<br>IEC-60601-1-1 (Ed2)<br>IEC-60601-1-2 Ed3:2007<br>NEMA UD-2 (2004)<br>IEC-62304 (2006)<br>ISO 14971 (2007)<br>ISO 10993-* | |

The following technical characteristics where differences exist were compared to determine if any new issues of safety and efficacy exists.

**1) Battery powered**

Marketing requires the device to have eight hours of battery life and be able to recharge overnight.

**2) Number of pressure, PVR, and PPG channel**

Marketing requires an option to cover the least expensive, the full coverage, and something in the middle. US Vascular and Viasonix marketing guys tend to disagree on the number of channels to provide at the desired price points. The number of channels has no effect diagnostically.

**3) 10 MHz Doppler Probe**

Marketing does not require the option of a 10 MHz probe.

**4) Doppler Performance**

US Vascular and Viasonix make no public claims to the sensitivity or accuracy of their Doppler probes. Bench testing shows the US Vascular Doppler to be as sensitive as the

Viasonix with significantly less power output. US Vascular power output has almost 200% tolerance to the FDA limits. The Viasonix power output has less than 10% tolerance.

**Non-Clinical Testing** **807.92(b)(1)**

The VascuLab VL40xx (VL 4000, VL40010, and VL4030) range of non-invasive peripheral vascular diagnostic systems have been subjected to Bio-Compatibility, Electrical Safety, Mechanical Safety, Acoustic Output, EMC emissions and immunity, and performance testing by certified laboratories. Internally the VL40xx is subjected to unit testing, verification, performance testing, and validation to ensure that the devices meet all of their functional specifications.

The VascuLab VL40xx (VL 4000, VL40010, and VL4030) range of non-invasive peripheral vascular diagnostic systems labeling includes instructions for safe and effective use, warnings, cautions and guidance for use. In addition, all of the warnings, cautions, and instructions for use are provided by the program for immediate online review by the user. It is therefore shown to be safe and effective.

**Conclusions** **807.92(b)(3)**

The conclusion drawn from these tests is that the VascuLab VL40xx (VL 4000, VL40010, and VL4030) range of non-invasive peripheral vascular diagnostic systems are equivalent in safety and efficacy to the predicate devices listed in the predicate product comparison table above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 27, 2013

Us Vascular, Llc
E.J. Smith
1468 Harwell Ave
Crofton, MD 21114 US

Re: K131860
Trade/Device Name: Vasculab vl4000 photoplethysmograph with pulse volume recording
Regulation Number: 21 CFR 870.2880
Regulation Name: Ultrasonic Transducer
Regulatory Class: Class II
Product Code: JOP
Dated: August 30, 2013
Received: August 30, 2013

Dear E.J. Smith:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Owen P. Faris -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use Form

## Indications for Use

510(k) Number (if known): _____

Device Name: _VL4000 (VL40XX)

Indications for Use:

The VL40xx is a Non-Invasive diagnostic system designed to detect peripheral vascular pathology in adults. In all cases the intended use is for spot checking and attended use by trained medical professionals in a hospital or medical facility by the order of a medical doctor.

The VL40xx is not intended to replace other means of evaluating vital patient physiological processes, is not intended to be used in fetal applications, and is not intended to be used inside the sterile field.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Page _1_ of __1_

Owen P. Faris -S

# Appendix G: Example Diagnostic Ultrasound Indications For Use Format

System: US Vascular Model VL40xx
Transducer: 4 MHz CW Model MTB HD.CW0400.02

Intended Use: Diagnostic ultrasound imaging or 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 | Combined (Specify) | Other* (Specify) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal | | | | | | | |
| | Abdominal | | | | | | | |
| | Intra-operative (Specify) | | | | | | | |
| | Intra-operative (Neuro) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | | | | | | | |
| | Small Organ (Specify) | | | | | | | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Card.) | | | | | | | |
| | Musculo-skeletal **(Conventional)** | | | | | | | |
| | Musculo-skeletal **(Superficial)** | | | | | | | |
| | Intravascular | | | | | | | |
| | Other (Specify) | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Intravascular (Cardiac) | | | | | | | |
| | Trans-esoph. (Cardiac) | | | | | | | |
| | Intra-cardiac | | | | | | | |
| | Other (Specify) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | N | | | |
| | Other (Specify) | | | | | | | |

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

# Appendix G: Example Diagnostic Ultrasound Indications For Use Format

System: US Vascular Model VL40xx
Transducer: 8 MHz CW Model MTB HD.CW0800.02

Intended Use: Diagnostic ultrasound imaging or 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 | Combined (Specify) | Other* (Specify) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal | | | | | | | |
| | Abdominal | | | | | | | |
| | Intra-operative (Specify) | | | | | | | |
| | Intra-operative (Neuro) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | | | | | | | |
| | Small Organ (Specify) | | | | | | | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Card.) | | | | | | | |
| | Musculo-skeletal **(Conventional)** | | | | | | | |
| | Musculo-skeletal **(Superficial)** | | | | | | | |
| | Intravascular | | | | | | | |
| | Other (Specify) | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Intravascular (Cardiac) | | | | | | | |
| | Trans-esoph. (Cardiac) | | | | | | | |
| | Intra-cardiac | | | | | | | |
| | Other (Specify) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | N | | | |
| | Other (Specify) | | | | | | | |

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