JUN 17 2010

K093466

Submitter Information

Submitter:	Hitachi Medical Systems America, Inc. 1959 Summit Commerce Park Twinsburg, Ohio 44087-2371 ph: (330) 425-1313 fax: (330) 963-0749
Contact:	Douglas J. Thistlethwaite
Date:	April 26, 2010

Device Name

Classification Name:	System, Imaging, Pulsed Doppler, Ultrasonic
Classification Number:	90-IYN
Trade/Proprietary Name:	HITACHI HI VISION Preirus Diagnostic Ultrasound Scanner
Predicate Device(s):	HI VISION 900 Diagnostic Ultrasound Scanner (K063518) GE Logiq® E9 (K082185) Acuson S2000 (K072786)

Device Intended Use

The HI VISION Preirus is intended for use by trained personnel (doctor, songrapher, etc.) for the diagnostic ultrasound evaluation of Abdominal, Cardiac, Intra-operative, Fetal, Pediatric, Small Organ, Peripheral vessel, Biopsy, Trans-rectal, Trans-vaginal, Musculoskeletal, Neonatal Cephalic, Adult Cephalic, Endoscopy, Intra-luminal, Gynecology, Urology and Laparoscopic clinical applications.

The Modes of Operation of the HI VISION Preirus are B mode, M mode, PW mode (Pulsed Wave Doppler), CW mode (Continuous Wave Doppler), Color Doppler, Amplitude Doppler (Color Flow Angiography), TDI (Tissue Doppler Imaging), 3D Imaging, 4D Imaging, Real Time Tissue Elastography, and Real Time Virtual Sonography..

Device Description

Function

An ultrasound system consists of the following:

- Ultrasound transducer(s) to generate the transmitted ultrasound energy and detect the reflected echoes
- A computer system to control the transducer and analyze the signals resulting from the reflected echoes
- A video monitor with optional image recorder to display the computed image or derived Doppler data

Scientific Concepts

An acoustic wave is a mechanical perturbation of a medium which passes through a given medium at a fixed velocity. The rate at which the particles in the medium vibrate in the disturbance is the frequency of the wave, and is measure as cycles/second, or hertz (Hz). Frequencies above 20 kHz are not audible, and above this frequency, the acoustic energy is known as ultrasound. For the purposes of medical ultrasound imaging, frequencies in the range of 1-20 MHz are utilized.

The ultrasound waves comprising a beam travel in as straight line in homogeneous media. When an ultrasound wave reaches an interface between two media of different impedances, a portion of the beam energy may pass through the boundary (transmission), and a portion may be reflected. The direction of propagation of the transmitted beam is determined by the angle of incidence of the incident beam upon the boundary, and differences (if any) in the speed of sound in the two media. The direction of reflection is determined solely by the angle of incidence upon the boundary. The relative strength of the reflected wave depends upon the differences in the impedances between the two media. Reflection at a boundary between soft tissue and bone, as an example, involves a large impedance difference, and results in a relatively strong reflected echo. Reflection at a boundary between two soft tissue-types with a relatively small impedance difference, on the other hand, results in a relatively weak reflected echo.

The ultrasound transducer, when operating in pulsed mode, periodically emits an ultrasound burst at a predetermined rate described as the pulse repetition frequency (PRF). During the time duration that the transducer is not transmitting ultrasound energy, it may act as a received for the reflected ultrasound energy. Since the speed of propagation of ultrasound in tissues is estimated as 1540m/sec, the time elapsed between transmission of a pulse and receipt of an echo may be used to estimate the distance from the transducer to the tissue structure giving rise to the reflected echo. The relative strength of the reflected echo can be used to determine the brightness of display of the reflected echo or strength of derived Doppler signal.

Physical and Performance Characteristics

The principle of operation of ultrasound imaging involves generation of an ultrasound wave with an electric signal applied to a transducer, direction of the resulting ultrasound wave into the tissue of the body, and reception and analysis of the echoes reflected back to the same or an adjacent transducer from the various tissues along the path of the ultrasound wave.

Device Technological Characteristics

The technological characteristics of this device are identical to the primary predicate device. The control and image processing hardware and the base elements of the system software are identical to the predicate device. See Section 4 – Predicate Device Comparison.

Conclusions

It is the opinion of Hitachi Medical Systems America, Inc. that HITACHI HI VISION Preirus Diagnostic Ultrasound Scanner is substantially equivalent to the predicate devices. In addition, we have concluded that the subject system is:

- Substantially equivalent with respect to safety, effectiveness, and functionality to the HI VISION 900 Diagnostic Ultrasound Scanner (K063518) with the exception of the two new Modes of Operation, Real Time Tissue Elastography and Real Time Virtual Sonography.
- Substantially equivalent with respect to safety and functionality to the GE Logiq® E9 (K082185) in regards to the device with Real-time Virtual Sonography (RVS)
- Substantially equivalent with respect to safety and functionality to the Acuson S2000 (K072786) in regards to the device with Real-time Tissue Elastography

Attachment

ATTACHMENT	POSITION
Declaration of Conformity with Design Controls	1

Summary of Design Control Activities

The design validation / verification tests that were performed are listed.

Items	Tests performed
Electrical, Mechanical safety	IEC60601-1[1] See section 1.7.2.1
Acoustic output safety	FDA Guidance IEC60601-2-37[2]
Software	See section 1.7.5
Probe patient contact materials	ISO10993[3] See section 1.7.3

[1] Medical Electrical Equipment, Part 1: General Requirements for Safety IEC60601-1

[2] Medical Electrical Equipment, Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment

[3] Biological Evaluation of Medical Device

DECLARATION OF CONFORMITY WITH DESIGN CONTROLS

Verification Activities

To the best of my knowledge, the verification activities, as required by the risk analysis, for the modification were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

Name: H. Noguchi

Title: Manager,
Ultrasound QA Section,
Hitachi Medical Corporation

Signature: H. Noguchi

Date: March 31, 2009

Manufacturing Facility

The manufacturing facility, Hitachi Medical Corporation is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.

Name: T. Kasanami

Title: Manager,
Development Design Dept.,
Ultrasound Systems Division,
Hitachi Medical Corporation

Signature: T. Kasanami

Date: March 31, 2009

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

JUN 17 2010

Mr. Doug Thistlethwaite
Manager, Regulatory Affairs
Hitachi Medical Systems America, Inc.
1959 Summitt Commerce Park
TWINSBURG OH 44087

Re: K093466
Trade/Device Name: Hitachi HI VISION Preirus Diagnostic Ultrasound Scanner
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: June 11, 2010
Received: June 15, 2010

Dear Mr. Thistlethwaite:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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). 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.

This determination of substantial equivalence applies to the following transducers intended for use with the Hitachi HI VISION Preirus Diagnostic Ultrasound Scanner, as described in your premarket notification:

Transducer Model Numbers

EUP-B512
EUP-B514
EUP-C514
EUP-C524
EUP-C532
EUP-C715
EUP-CC531
EUP-CV524
EUP-CV714
EUP-ES52E
EUP-L52
EUP-L53
EUP-L53L
EUP-L65
EUP-L73S
EUP-L74M
EUP-O54J
EUP-R54AW-19, -33

EUP-S50A	EUP-V53W
EUP-S52	EUP-VV731
EUP-S70	Fujinon SP711
EUP-U533	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosures

Indications for Use

510(k) Number (if known):

Device Name: **HI VISION Preirus Diagnostic Ultrasound Scanner**

Indications For Use:

The HI VISION Preirus is intended for use by trained personnel (doctor, songrapher, etc.) for the diagnostic ultrasound evaluation of Abdominal, Cardiac, Intra-operative, Fetal, Pediatric, Small Organ, Peripheral vessel, Biopsy, Trans-rectal, Trans-vaginal, Musculoskeletal, Neonatal Cephalic, Adult Cephalic, Endoscopy, Intra-luminal, Gynecology, Urology and Laparoscopic clinical applications.

The Modes of Operation of the HI VISION Preirus are B mode, M mode, PW mode (Pulsed Wave Doppler), CW mode (Continuous Wave Doppler), Color Doppler, Amplitude Doppler (Color Flow Angiography), TDI (Tissue Doppler Imaging), 3D Imaging, 4D Imaging, Real Time Tissue Elastography, and Real Time Virtual Sonography.

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

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

Concurrence of CDRH, Office ~~of Device Evaluation (ODE)~~ ODD

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093466

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Preirus

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	P
	Abdominal	Pa	Pa	Pa	Pa	Pa	Pa	Pa
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb	Pb	Pb
	Intra-operative (Neuro.)							
	Laparoscopic	P	P	P		P	P	P
	Pediatric	P	P	P	P	P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic	P	P	P		P	P	P
	Adult Cephalic	P	P	P	P	P	P	P
	Trans-rectal	Ph	Ph	Ph		Ph	Ph	Ph
	Trans-vaginal	Pf	Pf	Pf		Pf	Pf	Pf
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	P	P
	Musculo-skel. (Superfic.)	P	P	P		P	P	P
	Intra-luminal	P						
	Other (spec.)							
Cardiac	Cardiac Adult	P	P	P	P	P	P	P
	Cardiac Pediatric	P	P	P	P	P	P	P
	Trans-esophageal (card.)	Pg	Pg	Pg	P	Pg	Pg	Pg
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K063518.

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging, 3D Imaging, 4D Imaging, Real Time Tissue Elastography, Real Time Virtual Sonography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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

Concurrence of CDRH, Office of ~~Device Evaluation (ODE)~~ OIVD

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093466

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Preirus
Transducer: EUP-B512

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	P
	Abdominal	Pa	Pa	Pa	Pa	Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K063518.
*Combination of each operating mode, B, M, PWD and Color Doppler.
**Amplitude Doppler (Color Flow Angiography), Real Time Virtual Sonography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e": Includes imaging for guidance of transrectal biopsy.
Subscript "f": Includes imaging for guidance of transvaginal biopsy.
Subscript "g": For pediatric patients.
Subscript "h": Includes imaging for guidance of transrectal biopsy.

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

Concurrence of CDRH, Office of ~~Device Evaluation (ODE)~~ OIVD

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093466

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Preirus
Transducer: EUP-B514

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	P
	Abdominal	Pa	Pa	Pa	Pa	Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K063518.
*Combination of each operating mode, B, M, PWD and Color Doppler.
**Amplitude Doppler (Color Flow Angiography), Real Time Virtual Sonography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e": Includes imaging for guidance of transrectal biopsy.
Subscript "f": Includes imaging for guidance of transvaginal biopsy.
Subscript "g": For pediatric patients.
Subscript "h": Includes imaging for guidance of transrectal biopsy.

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

Concurrence of CDRH, Office of ~~Device Evaluation (ODE)~~ OIVD

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

Prescription Use (Per 21 CFR 801.109)

510K K093466

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Preirus
Transducer: EUP-C514

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K063518.
*Combination of each operating mode, B, M, PWD and Color Doppler.
**Amplitude Doppler (Color Flow Angiography), 3D Imaging, 4D Imaging, Real Time Virtual Sonography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e": Includes imaging for guidance of transrectal biopsy.
Subscript "f": Includes imaging for guidance of transvaginal biopsy.
Subscript "g": For pediatric patients.
Subscript "h": Includes imaging for guidance of transrectal biopsy.

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

Concurrence of CDRH, Office of ~~Device Evaluation (ODE)~~ - OIVD

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093466

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Preirus
Transducer: EUP-C524

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal	P	P	P		P	P	P
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pc	Pc	Pc		Pc	Pc	Pc
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K063518.
*Combination of each operating mode, B, M, PWD and Color Doppler.
**Amplitude Doppler (Color Flow Angiography), 3D Imaging, 4D Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e": Includes imaging for guidance of transrectal biopsy.
Subscript "f": Includes imaging for guidance of transvaginal biopsy.
Subscript "g": For pediatric patients.
Subscript "h": Includes imaging for guidance of transrectal biopsy.

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

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K: K093466

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Preirus
Transducer: EUP-C532

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb	Pb	Pb
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic	P	P	P		P	P	P
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K063518.
*Combination of each operating mode, B, M, PWD and Color Doppler.
**Amplitude Doppler (Color Flow Angiography), Real Time Tissue Elastography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e": Includes imaging for guidance of transrectal biopsy.
Subscript "f": Includes imaging for guidance of transvaginal biopsy.
Subscript "g": For pediatric patients.
Subscript "h": Includes imaging for guidance of transrectal biopsy.

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

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

Prescription Use (Per 21 CFR 801.109)

510K K093966

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Preirus
Transducer: EUP-C715

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K063518.
*Combination of each operating mode, B, M, PWD and Color Doppler.
**Amplitude Doppler (Color Flow Angiography), Real Time Virtual Sonography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e": Includes imaging for guidance of transrectal biopsy.
Subscript "f": Includes imaging for guidance of transvaginal biopsy.
Subscript "g": For pediatric patients.
Subscript "h": Includes imaging for guidance of transrectal biopsy.

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

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093466

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Preirus
Transducer: EUP-CC531

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	Pe	Pe	Pe		Pe	Pe	Pe
	Trans-vaginal	Pf	Pf	Pf		Pf	Pf	Pf
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K063518.
*Combination of each operating mode, B, M, PWD and Color Doppler.
**Amplitude Doppler (Color Flow Angiography), Real Time Tissue Elastography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e": Includes imaging for guidance of transrectal biopsy.
Subscript "f": Includes imaging for guidance of transvaginal biopsy.
Subscript "g": For pediatric patients.
Subscript "h": Includes imaging for guidance of transrectal biopsy.

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

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

Prescription Use (Per 21 CFR 801.109)

510K K093466

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Preirus
Transducer: EUP-CV524

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal	P	P	P		P	P	P
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	P	P	P		P	P	P
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K063518.
*Combination of each operating mode, B, M, PWD and Color Doppler.
**Amplitude Doppler (Color Flow Angiography), 3D Imaging, 4D Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e": Includes imaging for guidance of transrectal biopsy.
Subscript "f": Includes imaging for guidance of transvaginal biopsy.
Subscript "g": For pediatric patients.
Subscript "h": Includes imaging for guidance of transrectal biopsy.

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

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093466

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Preirus
Transducer: EUP-CV714

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal	P	P	P		P	P	P
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	P	P	P		P	P	P
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K063518.
*Combination of each operating mode, B, M, PWD and Color Doppler.
**Amplitude Doppler (Color Flow Angiography), 3D Imaging, 4D Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e": Includes imaging for guidance of transrectal biopsy.
Subscript "f": Includes imaging for guidance of transvaginal biopsy.
Subscript "g": For pediatric patients.
Subscript "h": Includes imaging for guidance of transrectal biopsy.

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

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093466

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Preirus
Transducer: EUP-ES52E

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)	P	P	P	P	P	P	P
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K063518.
*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.
**Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e": Includes imaging for guidance of transrectal biopsy.
Subscript "f": Includes imaging for guidance of transvaginal biopsy.
Subscript "g": For pediatric patients.
Subscript "h": Includes imaging for guidance of transrectal biopsy.

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

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093166

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Preirus
Transducer: EUP-L52

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	P	P
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K063518.
*Combination of each operating mode, B, M, PWD and Color Doppler.
**Amplitude Doppler (Color Flow Angiography), Real Time Tissue Elastography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e": Includes imaging for guidance of transrectal biopsy.
Subscript "f": Includes imaging for guidance of transvaginal biopsy.
Subscript "g": For pediatric patients.
Subscript "h": Includes imaging for guidance of transrectal biopsy.

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

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093466

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Preirus
Transducer: EUP-L53

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	P	P
	Musculo-skel. (Superfic.)	P	P	P		P	P	P
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K063518.
*Combination of each operating mode, B, M, PWD and Color Doppler.
**Amplitude Doppler (Color Flow Angiography), 3D Imaging, 4D Imaging, Real Time Tissue Elastography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e": Includes imaging for guidance of transrectal biopsy.
Subscript "f": Includes imaging for guidance of transvaginal biopsy.
Subscript "g": For pediatric patients.
Subscript "h": Includes imaging for guidance of transrectal biopsy.

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

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093466

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Preirus
Transducer: EUP-L53L

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P		P	P	P
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pc	Pc	Pc		Pc	Pc	Pc
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	P	P
	Musculo-skel. (Superfic.)	P	P	P		P	P	P
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K063518.
*Combination of each operating mode, B, M, PWD and Color Doppler.
**Amplitude Doppler (Color Flow Angiography), Real Time Tissue Elastography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e": Includes imaging for guidance of transrectal biopsy.
Subscript "f": Includes imaging for guidance of transvaginal biopsy.
Subscript "g": For pediatric patients.
Subscript "h": Includes imaging for guidance of transrectal biopsy.

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

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093466

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Preirus
Transducer: EUP-L65

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P		P	P	P
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pc	Pc	Pc		Pc	Pc	Pc
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	P	P
	Musculo-skel. (Superfic.)	P	P	P		P	P	P
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K063518.
*Combination of each operating mode, B, M, PWD and Color Doppler.
**Amplitude Doppler (Color Flow Angiography), Real Time Tissue Elastography, Real Time Virtual Sonography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e": Includes imaging for guidance of transrectal biopsy.
Subscript "f": Includes imaging for guidance of transvaginal biopsy.
Subscript "g": For pediatric patients.
Subscript "h": Includes imaging for guidance of transrectal biopsy.

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

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093466

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Preirus
Transducer: EUP-L73S

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic	-						
Fetal Imaging & Other	Fetal							
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	P	P
	Musculo-skel. (Superfic.)	P	P	P		P	P	P
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K063518.
*Combination of each operating mode, B, M, PWD and Color Doppler.
**Amplitude Doppler (Color Flow Angiography), Real Time Tissue Elastography, Real Time Virtual Sonography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e": Includes imaging for guidance of transrectal biopsy.
Subscript "f": Includes imaging for guidance of transvaginal biopsy.
Subscript "g": For pediatric patients.
Subscript "h": Includes imaging for guidance of transrectal biopsy.

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

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093466

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Preirus
Transducer: EUP-L74M

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	P	P
	Musculo-skel. (Superfic.)	P	P	P		P	P	P
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K063518.
*Combination of each operating mode, B, M, PWD and Color Doppler.
**Amplitude Doppler (Color Flow Angiography), Real Time Tissue Elastography, Real Time Virtual Sonography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e": Includes imaging for guidance of transrectal biopsy.
Subscript "f": Includes imaging for guidance of transvaginal biopsy.
Subscript "g": For pediatric patients.
Subscript "h": Includes imaging for guidance of transrectal biopsy.

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

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093466

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Preirus
Transducer: EUP-O54J

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb	Pb	Pb
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	P	P
	Musculo-skel. (Superfic.)	P	P	P		P	P	P
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K063518.
*Combination of each operating mode, B, M, PWD and Color Doppler.
**Amplitude Doppler (Color Flow Angiography), Real Time Tissue Elastography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e": Includes imaging for guidance of transrectal biopsy.
Subscript "f": Includes imaging for guidance of transvaginal biopsy.
Subscript "g": For pediatric patients.
Subscript "h": Includes imaging for guidance of transrectal biopsy.

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

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093466

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Preirus
Transducer: EUP-R54AW-19, -33

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	P	P
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K063518.
*Combination of each operating mode, B, M, PWD and Color Doppler.
**Amplitude Doppler (Color Flow Angiography), Real Time Tissue Elastography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e": Includes imaging for guidance of transrectal biopsy.
Subscript "f": Includes imaging for guidance of transvaginal biopsy.
Subscript "g": For pediatric patients.
Subscript "h": Includes imaging for guidance of transrectal biopsy.

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

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

Prescription Use (Per 21 CFR 801.109)

510K K093466

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Preirus
Transducer: EUP-S50A

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	P
	Abdominal	Pa	Pa	Pa	Pa	Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P	P	P	P	P
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P	P	P	P	P	P
	Cardiac Pediatric	P	P	P	P	P	P	P
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K063518.
*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.
**Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e": Includes imaging for guidance of transrectal biopsy.
Subscript "f": Includes imaging for guidance of transvaginal biopsy.
Subscript "g": For pediatric patients.
Subscript "h": Includes imaging for guidance of transrectal biopsy.

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

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093466

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Preirus
Transducer: EUP-S52

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P
	Small Organ (Spec.)	Pc	Pc	Pc	Pc	Pc	Pc	Pc
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric	P	P	P	P	P	P	P
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K063518.
*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.
**Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e": Includes imaging for guidance of transrectal biopsy.
Subscript "f": Includes imaging for guidance of transvaginal biopsy.
Subscript "g": For pediatric patients.
Subscript "h": Includes imaging for guidance of transrectal biopsy.

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

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093466

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Preirus
Transducer: EUP-S70

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	P
	Abdominal	P	P	P	P	P	P	P
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P	P	P	P	P
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P	P	P	P	P	P
	Cardiac Pediatric	P	P	P	P	P	P	P
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K063518.
*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.
**Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e": Includes imaging for guidance of transrectal biopsy.
Subscript "f": Includes imaging for guidance of transvaginal biopsy.
Subscript "g": For pediatric patients.
Subscript "h": Includes imaging for guidance of transrectal biopsy.

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

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093466

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Preirus
Transducer: EUP-U533

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	Ph	Ph	Ph		Ph	Ph	Ph
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K063518.
*Combination of each operating mode, B, M, PWD and Color Doppler.
**Amplitude Doppler (Color Flow Angiography), Real Time Tissue Elastography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e": Includes imaging for guidance of transrectal biopsy.
Subscript "f": Includes imaging for guidance of transvaginal biopsy.
Subscript "g": For pediatric patients.
Subscript "h": Includes imaging for guidance of transrectal biopsy.

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

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093466

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Preirus
Transducer: EUP-V53W

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	Pe	Pe	Pe		Pe	Pe	Pe
	Trans-vaginal	Pf	Pf	Pf		Pf	Pf	Pf
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K063518.
*Combination of each operating mode, B, M, PWD and Color Doppler.
**Amplitude Doppler (Color Flow Angiography), 3D Imaging, 4D Imaging, Real Time Tissue Elastography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e": Includes imaging for guidance of transrectal biopsy.
Subscript "f": Includes imaging for guidance of transvaginal biopsy.
Subscript "g": For pediatric patients.
Subscript "h": Includes imaging for guidance of transrectal biopsy.

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

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093466

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Preirus
Transducer: EUP-VV731

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	P	P
	Trans-vaginal	P	P	P		P	P	P
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K063518.
*Combination of each operating mode, B, M, PWD and Color Doppler.
**Amplitude Doppler (Color Flow Angiography)

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e": Includes imaging for guidance of transrectal biopsy.
Subscript "f": Includes imaging for guidance of transvaginal biopsy.
Subscript "g": For pediatric patients.
Subscript "h": Includes imaging for guidance of transrectal biopsy.

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

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093466

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Preirus
Transducer: Fujinon SP711

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal	P						
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K011252.

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e": Includes imaging for guidance of transrectal biopsy.
Subscript "f": Includes imaging for guidance of transvaginal biopsy.
Subscript "g": For pediatric patients.
Subscript "h": Includes imaging for guidance of transrectal biopsy.

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

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093466

Prescription Use (Per 21 CFR 801.109)