



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

Hitachi Aloka Medical America, Inc.  
% Ms. Angela Van Arsdale  
RA/QA Manager  
10 Fairfield Blvd.  
WALLINGFORD CT 06492

January 21, 2016

Re: K153421  
Trade/Device Name: HI VISION Ascendus  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed doppler imaging system  
Regulatory Class: II  
Product Code: IYN, IYO, ITX  
Dated: December 10, 2015  
Received: December 11, 2015

Dear Ms. Van Arsdale:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 For

Robert Ochs, Ph.D.  
Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K153421

Device Name

HI VISION Ascendus

Indications for Use (Describe)

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

The modes of operation of the HI VISION Ascendus are B mode, M mode, PW mode (Pulsed Wave Doppler), CW mode (Continuous Wave Doppler), Dual Doppler mode, CFI mode (Color Flow Image), Amplitude Doppler (Color Flow Angiography), TDI (Tissue Doppler Imaging), 3D Imaging, 4D Imaging, Real-time Virtual Sonography, Real-time Tissue Elastography and Shear Wave Measurement.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: All connectable probes

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

General (Track 1 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	Pc	Pd	Pd	Pd
	Neonatal Cephalic	P	P	P	P	P	P	P
	Adult Cephalic	P	P	P	P	P	P	P
	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.)	P	P	P		P	P	P
	Musculo-skel. (Superfic.)	P	P	P		P	P	P
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.)	Pg	Pg	Pg	Pg	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 K110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, B/CW, CFM-B/CW, CFM-B/CFM-B, CFM- B/CFM-M, CFM-B/PW, TDI-B/B, TDI-B/M, TDI-B/PW, TDI-PW/PW

\*\*Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging, 3D Imaging, 4D Imaging, Omni Directional M mode, Wide View, Real Time Biplane, Contrast Imaging, Real Time Tissue Elastography, Real Time Virtual Sonography, Shear Wave Measurement.

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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

*Prescription Use Only (per 21 CFR 801.109)*

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

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)

Division of Radiological Health

Office of In Vitro Diagnostic and Radiological Health

510(k) Number: \_\_\_\_\_

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-B512

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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							
	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 K1110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Wide View, Real Time Biplane, Contrast 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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

*Prescription Use Only (per 21 CFR 801.109)*

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Office of In Vitro Diagnostic and Radiological Health

510(k) Number: \_\_\_\_\_

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-B514

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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							
	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 K1110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Wide View, Real Time Biplane, Contrast 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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

*Prescription Use Only (per 21 CFR 801.109)*

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Division of Radiological Health

Office of In Vitro Diagnostic and Radiological Health

510(k) Number: \_\_\_\_\_

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-B712

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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							
	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 K110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, CFM-B/CFM-B, CFM- B/CFM-M, CFM-B/PW

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Wide View, Real Time Biplane, Contrast 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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

*Prescription Use Only (per 21 CFR 801.109)*

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Office of In Vitro Diagnostic and Radiological Health

510(k) Number: \_\_\_\_\_

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-B715

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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							
	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 K110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, CFM-B/CFM-B, CFM- B/CFM-M, CFM-B/PW

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Wide View, Real Time Biplane, Contrast 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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

*Prescription Use Only (per 21 CFR 801.109)*

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Office of In Vitro Diagnostic and Radiological Health

510(k) Number: \_\_\_\_\_

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-C511

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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.)							
	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	P	P	P		P	P	P
	Cardiac Pediatric	P	P	P		P	P	P
	Trans-esophageal (Card.)							
	Other (Spec.)							
Peripheral Vessel	Peripheral Vessel	P	P	P		P	P	P
	Other (Spec.)							

N= new indication P= previously cleared in K110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, CFM-B/CFM-B, CFM- B/CFM-M, CFM-B/PW

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Omni Directional M mode, Wide View, Real Time Biplane, Contrast 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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

*Prescription Use Only (per 21 CFR 801.109)*

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Office of In Vitro Diagnostic and Radiological Health

510(k) Number: \_\_\_\_\_

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-C514

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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 K1110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, CFM-B/CFM-B, CFM- B/CFM-M, CFM-B/PW

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Omni Directional M mode, Wide View, Real Time Biplane, Contrast 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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

*Prescription Use Only (per 21 CFR 801.109)*

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Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

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Division of Radiological Health

Office of In Vitro Diagnostic and Radiological Health

510(k) Number: \_\_\_\_\_

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-C524

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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 K1110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, CFM-B/CFM-B, CFM- B/CFM-M, CFM-B/PW

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Omni Directional M mode, Wide View, Real Time Biplane,

**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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

*Prescription Use Only (per 21 CFR 801.109)*

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Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)

Division of Radiological Health

Office of In Vitro Diagnostic and Radiological Health

510(k) Number: \_\_\_\_\_

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-C532

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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 K1110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, CFM-B/CFM-B, CFM- B/CFM-M, CFM-B/PW

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Wide View, Real Time Biplane, 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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

*Prescription Use Only (per 21 CFR 801.109)*

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Division of Radiological Health

Office of In Vitro Diagnostic and Radiological Health

510(k) Number: \_\_\_\_\_

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-C715

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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 K110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, CFM-B/CFM-B, CFM- B/CFM-M, CFM-B/PW

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Omni Directional M mode, Wide View, Real Time Biplane, Contrast Imaging, Real Time Tissue Elastography, Real Time Virtual Sonography, Shear Wave Measurement.

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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

*Prescription Use Only (per 21 CFR 801.109)*

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510(k) Number: \_\_\_\_\_

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-CC531

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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 K1110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, CFM-B/CFM-B, CFM- B/CFM-M, CFM-B/PW

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Biplane, Contrast 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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

*Prescription Use Only (per 21 CFR 801.109)*

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**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-CC531S

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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 K1110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, CFM-B/CFM-B, CFM- B/CFM-M, CFM-B/PW

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Biplane, Contrast 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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

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**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-CV524

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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 K1110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, CFM-B/CFM-B, CFM- B/CFM-M, CFM-B/PW

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, 4D Imaging, Omni Directional M mode

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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

*Prescription Use Only (per 21 CFR 801.109)*

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**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-CV714

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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 K1110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW.

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, 4D Imaging, Omni Directional M mode.

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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

*Prescription Use Only (per 21 CFR 801.109)*

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510(k) Number: \_\_\_\_\_

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-CV724

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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 K1110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW.

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, 4D Imaging, Omni Directional M mode.

**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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

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510(k) Number: \_\_\_\_\_

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-ES52E

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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 K1110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, B/CW, CFM-B/CW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW.

\*\*Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging, 3D Imaging, Omni Directional M mode.

**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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

*Prescription Use Only (per 21 CFR 801.109)*

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**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-ES52M

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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 K110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, B/CW, CFM-B/CW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW.

\*\*Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging, 3D Imaging, Omni Directional M mode.

**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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

*Prescription Use Only (per 21 CFR 801.109)*

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510(k) Number: \_\_\_\_\_

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-F334

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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	P	P	P		P	P	P
	Small Organ (Spec.)	Pc	Pc	Pc		Pc	Pc	Pc
	Neonatal Cephalic	P	P	P		P	P	P
	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	P	P	P		P	P	P
	Other (Spec.)							

N= new indication P= previously cleared in K1110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW.

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Wide View, Real Time Biplane.

**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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

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**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-F531

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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.)	Pb	Pb	Pb		Pb	Pb	Pb
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pc	Pc	Pc		Pc	Pc	Pc
	Neonatal Cephalic	P	P	P		P	P	P
	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	P	P	P		P	P	P
	Other (Spec.)							

N= new indication P= previously cleared in K1110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW.

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Wide View, Real Time Biplane.

**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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

*Prescription Use Only (per 21 CFR 801.109)*

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Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

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Division of Radiological Health

Office of In Vitro Diagnostic and Radiological Health

510(k) Number: \_\_\_\_\_

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-L52

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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 K1110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW.

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Omni Directional M mode, Wide View, Real Time Biplane, Contrast 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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

*Prescription Use Only (per 21 CFR 801.109)*

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510(k) Number: \_\_\_\_\_

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-L53

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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 K1110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW.

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Wide View, Real Time Biplane, 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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

*Prescription Use Only (per 21 CFR 801.109)*

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**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-L53L

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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 K1110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW.

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Wide View, Real Time Biplane, 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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

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**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-L54MA

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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 K1110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW.

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Omni Directional M mode, Wide View, Real Time Biplane, 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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

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510(k) Number: \_\_\_\_\_

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-L65

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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 K1110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW.

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging,Omni Directional M mode, Wide View, Real Time Biplane, 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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

*Prescription Use Only (per 21 CFR 801.109)*

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Office of In Vitro Diagnostic and Radiological Health

510(k) Number: \_\_\_\_\_

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-L73S

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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 K1110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW.

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Omni Directional M mode, Wide View, Real Time Biplane, Contrast 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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

*Prescription Use Only (per 21 CFR 801.109)*

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Office of In Vitro Diagnostic and Radiological Health

510(k) Number: \_\_\_\_\_

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-L74M

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

General (Track 1 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 K1110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW.

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Omni Directional M mode, Wide View, Real Time Biplane, Contrast 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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

*Prescription Use Only (per 21 CFR 801.109)*

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

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Office of In Vitro Diagnostic and Radiological Health

510(k) Number: \_\_\_\_\_

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-L75

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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	
	Other (Spec.)							

N= new indication P= previously cleared in K1110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW.

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Omni Directional M mode, Wide View, Real Time Biplane, 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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

*Prescription Use Only (per 21 CFR 801.109)*

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**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-LV74

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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 K1110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW.

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, 4D Imaging, Omni Directional M mode, 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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

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**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-053T

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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.)							
	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 K110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW.

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Wide View, Real Time Biplane, Contrast 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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

*Prescription Use Only (per 21 CFR 801.109)*

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Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

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Division of Radiological Health

Office of In Vitro Diagnostic and Radiological Health

510(k) Number: \_\_\_\_\_

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-054J

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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 K1110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW.

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Omni Directional M mode, Wide View, Real Time Biplane, 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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

*Prescription Use Only (per 21 CFR 801.109)*

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Office of In Vitro Diagnostic and Radiological Health

510(k) Number: \_\_\_\_\_

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-0732T

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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.)	P	P	P		P	P	P
	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 K110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW.

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Wide View, Real Time Biplane, Contrast 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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

*Prescription Use Only (per 21 CFR 801.109)*

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510(k) Number: \_\_\_\_\_

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-OL334

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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	P	P	P		P	P	P
	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 K1110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW.

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Wide View, Real Time Biplane, Contrast 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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

*Prescription Use Only (per 21 CFR 801.109)*

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510(k) Number: \_\_\_\_\_

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-R54AW-19, -33

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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 K1110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW.

\*\*Amplitude Doppler (Color Flow Angiography), 3D 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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

*Prescription Use Only (per 21 CFR 801.109)*

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510(k) Number: \_\_\_\_\_

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-S50A

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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 K110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, B/CW, CFM-B/CW, CFM-B/CFM-B, CFM- B/CFM-M, CFM-B/PW, TDI-B/B, TDI-B/M, TDI-B/PW, TDI-PW/PW.

\*\*Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging, 3D Imaging, Omni Directional M mode, Contrast 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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

*Prescription Use Only (per 21 CFR 801.109)*

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510(k) Number: \_\_\_\_\_

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-S52

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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 K110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, B/CW, CFM-B/CW, CFM-B/CFM-B, CFM- B/CFM-M, CFM-B/PW, TDI-B/B, TDI-B/M, TDI-B/PW, TDI-PW/PW

\*\*Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging, 3D Imaging, Omni Directional M mode, Real Time Biplane.

**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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

*Prescription Use Only (per 21 CFR 801.109)*

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Office of In Vitro Diagnostic and Radiological Health

510(k) Number: \_\_\_\_\_

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-S70

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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 K110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, B/CW, CFM-B/CW, CFM-B/CFM-B, CFM- B/CFM-M, CFM-B/PW, TDI-B/B, TDI-B/M, TDI-B/PW, TDI-PW/PW

\*\*Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging, 3D Imaging, Omni Directional M mode, Real Time Biplane, Contrast 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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

*Prescription Use Only (per 21 CFR 801.109)*

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Office of In Vitro Diagnostic and Radiological Health

510(k) Number: \_\_\_\_\_

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-S72

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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	P
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P
	Small Organ (Spec.)							
	Neonatal Cephalic	P	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	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							
	Other (Spec.)							

N= new indication P= previously cleared in K110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, B/CW, CFM-B/CW, CFM-B/CFM-B, CFM- B/CFM-M, CFM-B/PW, TDI-B/B, TDI-B/M, TDI-B/PW, TDI-PW/PW

\*\*Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging, 3D Imaging, Omni Directional M mode, Wide View, Real Time Biplane.

**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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

*Prescription Use Only (per 21 CFR 801.109)*

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510(k) Number: \_\_\_\_\_

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-S80

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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 K1110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, B/CW, CFM-B/CW, CFM-B/CFM-B, CFM- B/CFM-M, CFM-B/PW, TDI-B/B, TDI-B/M, TDI-B/PW, TDI-PW/PW

\*\*Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging, 3D Imaging, Omni Directional M mode, Real Time Biplane, Contrast 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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

*Prescription Use Only (per 21 CFR 801.109)*

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**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-U533

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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	Pe	Pe	Pe		Pe	Pe	Pe
	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 K110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW.

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Wide View, Real Time Biplane, 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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

*Prescription Use Only (per 21 CFR 801.109)*

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

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

\_\_\_\_\_  
(Division Sign-Off)

Division of Radiological Health

Office of In Vitro Diagnostic and Radiological Health

510(k) Number: \_\_\_\_\_

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-V53W

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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 K1110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW.

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Wide View, Real Time Biplane, Contrast 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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

*Prescription Use Only (per 21 CFR 801.109)*

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Division of Radiological Health

Office of In Vitro Diagnostic and Radiological Health

510(k) Number: \_\_\_\_\_

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-V73W

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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 K1110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW.

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Wide View, Real Time Biplane, Contrast 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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

*Prescription Use Only (per 21 CFR 801.109)*

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510(k) Number: \_\_\_\_\_

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-VV531

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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 K1110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW.

\*\*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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

Prescription Use Only (per 21 CFR 801.109)

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Office of In Vitro Diagnostic and Radiological Health

510(k) Number: \_\_\_\_\_

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: HI VISION Ascendus

Transducer: EUP-VV731

Intended Use: Diagnostic ultrasound imaging or find flow analysis if the human body as follows:

Clinical Application								
General (Track 1 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 K1110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, PW/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW.

\*\*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 trans-rectal biopsy.

Subscript "f": Includes managing for guidance of trans-vaginal biopsy.

Subscript "g": For Adults and Pediatric patients.

*Prescription Use Only (per 21 CFR 801.109)*

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Office of In Vitro Diagnostic and Radiological Health

510(k) Number: \_\_\_\_\_

**510(k) Summary of Safety and Effectiveness in accordance with  
21 CFR Part 807, Subpart E, Section 807.92.**

21 CFR 807.92, Subsection a

1. Submitter's Information

Hitachi Aloka Medical America, Inc.  
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Wallingford, CT 06492-5903  
On behalf of  
HITACHI MEDICAL CORPORATION  
4-14-1, Soto-Kanda, Chiyoda-Ku,  
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Regulatory Affairs Product Specialist  
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Date Prepared: November 23, 2015

2. Device / Common / Classification Name / Classification / Product Code:

Device Proprietary Name – HI VISION Ascendus  
Common name - Diagnostic Ultrasound System and Transducers  
Classification name - System, Imaging, Pulsed Doppler, Ultrasonic  
Classification: Class II  
Product Code: 90-IYN 892.1550 Ultrasonic Pulsed Imaging System  
90-IYO 892.1560 Ultrasonic Pulsed Echo Imaging System  
90-ITX 892.1570 Diagnostic Ultrasound Transducer

3. Legally Marketed Predicate Device(s):

HI VISION Ascendus (K110673)  
Noblus (K142368)  
Siemens Acuson S2000/S3000 (K130881)

4. Device Description:

- An ultrasound diagnostic system with the following features:
- Ultrasound transducer(s) – to generate the transmitted ultrasound energy and detect the reflected echoes
  - Ultrasound transducer accessories (standard and optional) - to maximize functional usage of transducer(s) in various modes of operation
  - 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

5. Indication for Use:

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

The modes of operation of the HI VISION Ascendus are B mode, M mode, PW mode (Pulsed Wave Doppler), CW mode (Continuous Wave Doppler), Dual Doppler mode, CFI mode (Color Flow Image), Amplitude Doppler (Color Flow Angiography), TDI (Tissue Doppler Imaging), 3D Imaging, 4D Imaging, Real-time Virtual Sonography, Real-time Tissue Elastography and Shear Wave Measurement.

6. Comparison to predicate device:

The Hitachi HI VISION Ascendus Ultrasound Electronic Scanner is equivalent to the predicate devices the Hitachi HI VISION Ascendus (K110673). The HI VISION Ascendus has been modified to include features from both the Noblus (K142368) and Siemens S2000/S3000( K130881). The subject and predicate devices are Track III systems.

	<b>Predicate Device HI VISION ASCENDUS (K110673)</b>	<b>Predicate Device Noblus (K142368)</b>	<b>Predicate Device Siemens ACUSON S2000/S3000 (K130881)</b>	<b>Subject Device HI VISION ASCENDUS</b>
Intended Use:	Intended for use for Fetal, Abdominal, Intra-operative (Spec.), Intra-operative (Neuro.), Laparoscopic, Pediatric, Small Organ (Spec.), Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-Vaginal, Musculo-skel. (Convent.), Musculol-skel. (Superfic.), Cardiac Adult, Cardiac Pediatric, Trans-esophageal (card.), Peripheral vessel.  The modes of operation are B mode, M mode, PWD (Pulsed Wave Doppler) mode, CWD (Continuous Wave Doppler) mode, Color Doppler, Amplitude Doppler, Harmonic Imaging, Superficial musculoskeletal imaging, and 3D Imaging	Intended for use by trained personnel (doctor, sonographer, etc.) for the diagnostic ultrasound evaluation of Abdominal, Cardiac, Intra-operative, Fetal, Pediatric, Small Organ, Peripheral vessel, Biopsy, Trans-rectal, Trans-vaginal, Neonatal Cephalic, Adult Cephalic, Intra-luminal, Gynecology, Urology and Laparoscopic clinical applications.  The main features on Noblus are B mode, M mode, PW mode (Pulsed Wave Doppler), CW mode (Continuous Wave Doppler), CFI mode (Color Flow Image), TDI (Tissue Doppler Imaging) and Real-time Tissue Elastography	Intended for the following applications: Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Transcranial, OB/GYN, Cardiac, Pelvic, Neonatal/Adult Cephalic, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.	Intended for use for Fetal, Abdominal, Intra-operative (Spec.), Laparoscopic, Pediatric, Small Organ (Spec.), Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-Vaginal, Musculo-skel. (Convent.), Musculol-skel. (Superfic.), Cardiac Adult, Cardiac Pediatric, Trans-esophageal (card.), Peripheral vessel.  <i>The modes of operation are B mode, M mode, PWD (Pulsed Wave Doppler) mode, CWD (Continuous Wave Doppler) mode, Color Doppler, Amplitude Doppler, Harmonic Imaging, Superficial musculoskeletal imaging, and 3D Imaging.</i>
FDA Track:	3	3	3	3
*Probes:	Convex, Linear, Sector, 4D, Other	Convex, Linear, Sector, 4D, Other, EUS	Convex, Linear, Sector, Other	Convex, Linear, Sector, 4D, Other
Display Modes:	Combinations of B, M, PW, CW	Combinations of B, M, PW, CW	Unknown	Combinations of B, M, PW, CW
Real-time Tissue Elastography (RTTE) with *STRAIN RATIO/STRAIN HISTOGRAM*	RTTE only	Real-time Tissue Elastography (RTTE) with <b>STRAIN RATIO/STRAIN HISTOGRAM</b>	Applicable	Real-time Tissue Elastography (RTTE) with <b>STRAIN RATIO/STRAIN HISTOGRAM</b>
<b>SHEAR WAVE ELASTOGRAPHY MEASUREMENT (SWM)*</b>	N/A	N?A	Applicable	<b>SHEAR WAVE ELASTOGRAPHY MEASUREMENT</b>
a*RTTE and SWM features will be added to the ARIETTA70 (K134016) and next generation ultrasound systems				

21 CFR Part 807.92, Section b

1. Non-clinical Testing

No new hazards were identified with the subject device. The subject device and its transducers have been evaluated for acoustic output, biocompatibility, cleaning & disinfection effectiveness, electromagnetic compatibility, as well as electrical and mechanical safety, and have been found to conform to applicable medical device safety standards.

2. Clinical testing:

None required

3. Conclusions:

The HI VISION Ascendus Diagnostic Ultrasound scanner is substantially equivalent in safety and effectiveness to the predicate device(s);

- The subject and predicate device(s) are both indicated for diagnostic ultrasound imaging and fluid flow analysis.
- The subject and predicate device(s) have the same gray scale and Doppler capabilities.
- The subject and predicate device(s) have the same essential technology for imaging, Doppler functions, and signal processing.
- The subject and predicate device(s) have acoustic level below the Track 3 FDA limits.
- The subject and predicate device(s) are manufactured in accordance to FDA 21 CFR 820 Quality System Regulations.
- The subject and predicate device(s) are designed and manufactured to the same electrical and physical safety standards.
- The subject and predicate device(s) are manufactured with materials that have been tested in accordance to ISO 10993-1; all biocompatibility testing has been conducted in accordance to each component material characterization, type of body contact, and duration contact risk profile.
- The subject and predicate device(s) are designed to be re-usable and provide instructions for cleaning, disinfection, and sterilization in the Ultrasound system and transducer manuals.

**END OF SUMMARY**