# **Device Description**

The Hitachi HI VISION 900 Diagnostic Ultrasound Scanner is a Track 3 Diagnostic Ultrasound Pulsed Doppler and Pulsed Echo Imaging System capable of the following operating functions:

B Mode

- M Mode
- Pulsed Wave Doppler
- Continuous Wave Doppler

Color Flow

- Amplitude Doppler
- Harmonic imaging
- Superficial musculoskeletal imaging
- 3D imaging

# Safety

As a Track 3 ultrasound device, the Hitachi HI VISION 900 Diagnostic Ultrasound Scanner complies with the *Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment (1992) – published by NEMA as UD-3.* 

With respect to limits on acoustic outputs, the Hitachi HI VISION 900 Diagnostic Ultrasound Scanner complies with the guideline limits set in the *510(k) Diagnostic Ultrasound Guidance – Revision: April 14, 1994.* 

With regard to general safety, the Hitachi HI VISION 900 Diagnostic Ultrasound Scanner is designed to comply with *IEC 606601-1 (1998) Medical Electrical Equipment, Part 1 – General Requirements for Safety.* 

ī.



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

ľ

DEC 2 1 2006

Mr. Douglas J. Thistlewaite Manager of Regulatory Affairs HITACHI Medical Systems America, Inc. 1959 Summit Commerce Park TWINSBURG OH 44087-2371

Re: K063518

Trade Name: HI VISION 900 Diagnostic Ultrasound Scanner Regulation Number: 21 CFR 892.1550 Regulation Name: Ultrasonic pulsed doppler imaging system Regulation Number: 21 CFR 892.1560 Regulation Name: Ultrasonic pulsed echo imaging system Regulation Number: 21 CFR 892.1570 Regulation Name: Diagnostic ultrasonic transducer Regulatory Class: II Product Code: IYN, IYO, and ITX Dated: November 20, 2006 Received: November 21, 2006

Dear Mr. Thistlewaite:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the HI VISION 900 Diagnostic Ultrasound Scanner, as described in your premarket notification:



Protecting and Promoting Public Health

#### Transducer Model Number EUP<u>-B514</u> EUP-F531 EUP-S50 EUP-C514 EUP-L53S EUP-TC3 **EUP-C532** EUP-L65 EUP-U533 EUP-CC531 EUP-O53T EUP-V53W EUP-CV524 EUP-OL334 EUP-ES52M EUP-R54AW-19, -33

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

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

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

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

Page 2 – Mr. Thistlewaite

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <u>http://www.fda.gov/cdrh/industry/support/index.html</u>

If you have any questions regarding the content of this letter, please contact Andrew Kang at (240) 276-3666.

Sincerely yours,

and a desom

Nancy C. Brogdon Director, Division of Reproductive, Abdominal and Radiological Devices Office of Device Evaluation Center for Devices and Radiological Health

Enclosure(s)

### System:

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM HI VISION 900

Clinical Application		Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)	
Ophthalmic	Ophthalmic	· · ·							
	Fetal	Ň	N	N	N	N	N	N	
	Abdominal	Na	Na	Na_	Na	Na	Na	Na	
	Intra-operative (Spec.)	Nb	Nb	Nb		Nb	Nb	Nb	
	Intra operative (Neuro.)								
	Laparoscopic	N	N	N		N	N	N	
	Pediatric	N	N	N	N	N	N	<u>N</u>	
	Small Organ (Spec.)	Nd	Nd	Nd		Nd	Nd	Nd	
	Neonatal Cephalic	N	N	N		N	N	N	
Fotal Imaging	Adult Cephalic	N	N	N	N	N	N	N	
& Other	Trans-rectal	Nh	Nh	Nh		Nh	Nh	Nh	
•	Trans-vaginal	Nf	Nf	Nf		Nf	Nf	Nf	
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)	N	N	N		N	N	N	
	Musculo-skel. (Superfic.)	N	Ň	N		N	N	N	
	Intra-luminal	ľ							
	Other (spec.)			1					
	Cardiac Adult	N	N	N	N	N	N	N	
Cardiac	Cardiac Pediatric	N	N	N	Ň_	N	N	N	
	Trans esophageal (card.)	Ng	Ng	Ng	N	Ng	Ng	Ng	
	Other (spec.)								
Peripheral	Peripheral vessel	N	N	N	N	N	N	N	
Vessel	Other (spec.)								

	Intended use: Diagnostic ultrasound imagi	ing or fluid flow analysis if the human body as follows:
1	Clinical Application	Mode of Operation

N = new indication, P = previous indication

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

\*\*Amplitude Doppler, Harmonic Imaging and 3D Imaging.

Additional Comments: Subscript "a": Include

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).

	texcluding heurosurgery and imparoscopic procedures.
Subscript 'c'	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f"	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Division of Reproductive, Abdominal, ENT, and Radiological Devices

2063518 510(k) Number:

Prescription Use (Per 21 CFR 801.109)

67202960221+

From-Hitachi Medical Systems America

90-61-ceQ

meS⊅:S∣

System: HI VISION 900

Transducer: EUP-B514

Clinical Application		Mode of Operation								
General (Track I only)	Specific (Tracks I & III)	B	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthulmic	Ophthalmic									
	Fetal	- ¥ -	P	P		P	P P	P		
	Abdominal	Pa	Pa	P		Pa	Pa	Pa		
	Intra-operative (Spec.)									
	Intra-operative (Neuro.)						<u> </u>			
	Laparoscopic			1			· · · · ·			
	Pediatric									
	Small Organ (Spec.)									
	Neonatal Cephalic						<u>├────</u>			
Fetal Imaging	Adult Cephalic						1			
& Other	Trans-rectal									
	Trans-vaginal							·		
	Trans-urethral									
	Trans-esoph. (non-Card.)					· · · · · · · · · · · · · · · · · · ·				
	Musculo-skel. (Convent.)									
	Musculo-skel. (Superfic.)									
	Intra-luminal							·····		
	Other (spec.)									
	Cardiac Adult							<u></u>		
Cardiac	Cardiac Pediatric									
	Trans-esopbageal (card.)									
	Other (spec.)						1			
Peripheral	Peripheral vessel						1			
Vessel	Other (spec.)						<u> </u>			

#### Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human hody as follows: Clinical Analisasia

N = new indication, P = previous indication\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler and Harmonic 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
<u></u>	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy
Subscript "e"	Includes imaging for guidance of transrectal biopay.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g"	For pediatric patients.
Subscript "h"	Includes imaging for guidance of transrectal biopsy.
PLEAS	SE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Division of Reproductive, Abdominal, ENT. and Radiological Devices

510(k) Number:

(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices 510(k) Number

Prescription Use (Per 21 CFR 801.109)

P.005/020 F-891 880-1

67206980861+

M5242am

System: Transducer:

HI VISION 900
EUP-C514

Clinical Application			Mode of Operation								
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)			
Ophthalmic	Ophthalmic	i									
	Fetal	P	P	P		9	P ]	P			
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa			
	Intra operative (Spec.)										
i	Intra-operative (Neuro.)										
	Laparoscopic			1							
	Pediatric	· P	P	P		P	P	P			
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd			
	Neonatal Cephalic										
	Adult Cephalic										
& Other	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)										
	Musculo-skel. (Superfic.)										
	Intra-luminal										
	Other (spec.)										
	Cardiac Adult										
Cardiac	Cardiac Pediatric										
	Trans-esophageal (card.)										
	Other (spec.)										
Peripheral	Peripheral vessel										
Vessel	Other (spec.)										

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

N = new indication, P = previous indication

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

\*\*Amplitude Doppler, Harmonic Imaging and 3D Imaging.

Additional Comments

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

Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c"	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h"	Includes imaging for guidance of transpectal biopsy.
(PLEAS	SE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number:

(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices 510(k) Number

Prescription Use (Per 21 CFR 801.109)

Dec-19-06 Stam From-Hitschi Medical Systems America

System: Transducer:

	HI VISION 900	
er;	EUP-C532	

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

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

N = new indication, P = previous indication

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

\*\*Amplitude Doppler and Harmonic Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures

	(including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.
(PLEAS	SE DO NOT WRITE BRLOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Division of Reproductive, Abdominal, ENT. and Radiological Devices

(0 510(k) Number: Sum

(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices 510(k) Number

Prescription Use (Per 21 CFR 801.109)

Dec-19-06 12:43am From-Hitachi Medical Systems America

System: Transducer: HI VISION 900 EUP-CC531

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

Mode of Operation **Clinical Application** General B Μ PWD CWD Color Combined Other\*\* Specific (Track I only) (Tracks I & III) Doppler (Spec.) (Spec.) Ophthalmic Ophthalmic Ρ Ρ P P P Fetal P Abdominal Intra operative (Spec.) Intra operative (Neuro.) Laparoacopic Pediatric Small Organ (Spec.) Neonatal Cophalic Fetal Imaging Adult Cephalic & Other Trans-rectal Pe Pe Pe Pe Pe Pe  $\frac{1}{10}$ **P**f Pf Pf Pf Pf Trans-vaginal Trans-urethral Trans-esoph. (non-Card.) Musculorskel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.) Cardiac Adult Cardiac **Cardiac Pediatric** Trans-esophageal (card.) Other (spec.) Peripheral vessel Peripheral Vessel Other (spec.)

N = new indication, P = previous indication

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

\*\*Amplitude Doppler and Harmonic Imaging

Additional Comments:

Subscript "a":	Includes imaging for	guidance of percutaneo	us biopsy of abdominal org	ans and structures
	(including amniocente	esis).	· · · ·	

Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subacript "I":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.
	TE DO NOT HENER DELOUGHT INE CONTINUE ON ANOTHER DACE IF NEEDED)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

> (Division Sign-Off) Division of Reproductive, Abdominal, ENT, and Radiological Devices

c063518 510(k) Number: 4. Storm

(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices 510(k) Number \_\_\_\_

Prescription Use (Per 21 CFR 801.109)

C

System: Transducer:

# HI VISION 900 EUP-CV524

Chr	Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
	Fetal	Р	P	P		P	P	P
	Abdominal	P	P	P		P	P	P
	Intra-operative (Spcc.)		<u> </u>	1				
	Intra-operative (Neuro.)			1				<u> </u>
	Laparoscopic			1				
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Р	P	P		P	P	P
	Neonatal Cephalic						+ <b>-</b>	
Fetal Imaging	Adult Cephalic					~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		
& Other	Trans-rectal			†				
	Trans-vaginal						<u>┾────</u> ┼	
	Trans-urethral							
-	Trans-esoph. (non-Card.)						<u> </u>	· · · · · · · · · · · · · · · · · · ·
	Musculo-skel. (Convent.)						┼╾┈────┼┼╎	
	Musculo skel. (Superfic.)							
	Intra-luminal		· · · · ·	<u> </u>				
	Other (spec.)	<u> </u>		<b> </b>			<u> </u>	
بدي يزير بي منطقي عن الكري	Cardiac Adult							
Cardiac	Cardiac Pediatric	· · · ·					<u>                                      </u>	
	Trans'esophageal (card.)						<u>├</u>	
	Other (spec.)			<u> </u>		·····		
Peripheral	Peripheral vessel			<u> </u>				
Vessel	Other (spec.)							

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

N = new indication, P = previous indication

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

\*\*Amplitude Doppler, Ĥarmonic Imaging and 3D Imaging.

## Additional Comments:

Subscript "A":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocantesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c"-	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e"	Includes imaging for guidance of transrectal biopsy.
Subscript "I"	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients
Subscript "h'	Includes imaging for guidance of transrectal biopsy.
DIFAC	T DO NOT WE WE DELOW FINE LINE CONTRACTOR ON A DOMESTIC ON AN ADDRESS

(PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number:

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices 510(k) Number \_

Prescription Use (Per 21 CFR 801.109)

67206960661+

From-Hitachi Medical Systems America N664:21

Transducer: EUP·ES52M

System:

Clin	ical Application	Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color	Combined*	Other**
Ophthalmic	Ophthalmic		┨╼╌┅╼╼╼	+		Dopplor	(Spec.)	(Spec.)
	Fetal		<del> </del>			· · · · · · · · · · · · · · · · · · ·	+ +	
	Abdominal			1			+	
	Intra operative (Spec.)		<u> </u>				<u> </u>	···
	Intra operative (Neuro.)		1	+			<u> </u>	
	Laparoscopic		÷ -	+	[f		┿┯╴╴╴╺┢	
	Pediatric			1		· · · · · · ·	- <u> </u> -	
	Small Organ (Spec.)						<u> </u>	
]	Neonatal Cephalic							
Fetal Imaging	Adult Cephalic		1	1	·			
& Other	Trans-rectal		·		. 1			
	Trans-vaginal			1	1 1			
	Trans-urethral		1	1			1	
	Trans-esoph. (non-Card.)	·	1	1			**************************************	
	Musculo-skel. (Convent.)							
]	Musculo-skel. (Superfic.)		I					
	Intra-luminal							
	Other (spec.)					· · ·		
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)	Р	P_	<u> </u>	P	Р	P	P
	Other (spec.)		1					
Peripheral	Peripheral vessel							
Vessel	Other (spec.)							

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

N = new indication, P = previous indication

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

\*\*Amplitude Doppler

Additional Comments:

Subscript "a": Includes imaging for guidance of percutancous biopsy of abdominal organs and structures

	Uncluding ampiocentosis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(axcluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "I"	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.
(PLEA	SE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Division of Reproductive, Abdominal, ENT, and Radiological Devices

D 510(k) Number:

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices K06351 510(k) Number

Prescription Use (Per 21 CFR 801,109)

1Ò

### DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM HI VISION 900 EUP-F531

System: Transducer:

#### **Clinical Application** Mode of Operation General Specific B М PWD CWD Color Combined\* Other\*\* (Tracks I & III) (Track 1 only) Doppler (Spec.) (Spec.) Ophthalmic Ophthalmic Fetal Abdominal P P P ñ P P Pb Pb Intra-operative (Spec.) Pb Pb Рb Pb Intra operative (Neuro.) Laparoscopic Pediatric P P P P P P Small Organ (Spec.) Neonatal Cephalic Pc Pc Pc Pc Pc Pc P P P P Ρ P Fetal Imaging Adult Cephalic & Other Trans-rectal P P P р Þ P Trans vaginal P P Ŗ P P P Trans-urethral Trans-esoph, (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra luminal Other (spec.) Cardiac Adult Cardiac Cardiac Pediatric Trans-esophageal (card.) Other (spec.) Peripheral Peripheral vessel P Ρ Р P Ρ Vessel Other (spec.)

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

N = new indication, P = previous indication

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

\*\*Amplitude Doppler and Harmonic 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, perus and imaging for guidance of biopsy.
Subscript "e"	Includes imaging for guidance of transrectal biopsy.
Subscript "f"	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy,
(PLEAS	SE DO NOT WRITE BELOW THIS I INF-CONTINUE ON ANOTHER DACE IN MERDED

ASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number:

the Ara

K063518

(Division Sign-Off) **1** Division of Reproductive, Abdominal, and Badiological Devices 510(k) Number <u>KICC</u> 3518

Prescription Use (Per 21 CFR 801.109)

1-083 b 011/020 E-001

67206960681+

System: Transducer:

	HI VISION 900
1	EUP-L58S

U.I.I.	Chinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)	
Ophthalmic	Ophthalmic								
	Fetal Abdominal	Pa	Pa	Pa		Pa	Pa	Pa	
	Intra operative (Spec.) Intra operative (Neuro.)	· · · · · · · · ·							
	Laparoscopic Pediatric	P	Р	P		Р	P	Р	
	Small Organ (Spec.) Neonatal Cephalic	Pd	Pd	Pd		Pd	Pd	Pd	
Fetal Imaging & Other	Adult Cephalic Trans-rectal		· · · · · · · · · · · · · · · · · · ·						
di Quiler	Trans-vaginal	·····						····	
	Trans-urethral Trans-esoph. (non-Card.)						· · · · · · · · · · · · · · · · · · ·		
	Musculo-skel (Convent.) Musculo-skel (Superfic.)	2 P	P P	P P		4 9	P P	<u>Р</u> Р	
	Intra-luminal Other (spec.)								
Cardiac	Cardiac Adult			<u> </u>			· · · · · · · · · · · · · · · · · · ·		
Uarolac	Cardiac Pediatric Trans-esophageal (card.)			···					
Peripheral	Other (spec.) Peripheral vessel	Р	P	P		P	P	P	
Vessel	Other (spec.)			-		· · · · · · · · · · · · · · · · · · ·			

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

N = new indication, P = previous indication

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

\*\*Amplitude Doppler, Harmonic Imaging and 3D Imaging.

Additional Comments:

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

Subscript "b"	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f"	Includes imaging for guidance of transvaginal biopsy.
Subacript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.
(DI P) (	TO NOT WRITE DELOW THIS LIVE CONTINUE ON ANOTHER DATES

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

> (Division Sign-Off) Division of Reproductive, Abdominal, ENT, and Radiological Devices

K063518 510(k) Number:

(Division Sign-Off) Division of Reproductive, Abdominal, and Reduclogical Devices

Prescription Use (Per 21 CFR 801.109)

System: Transducer:

# EUP-L65

	Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	B	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic	•						
	Fetal							
	Abdominal	P	P	P		P	P +	P
	Intra-operative (Spec.)					<u> </u>		
	Intra operative (Neuro.)							
	Laparoscopic			·				
	Pediatric	P	P	L P		P	P P	Р
	Small Organ (Spec.)	Pc	Pc	Pc		Pc	Pc	Pc
	Neonatal Cephalic	[						
Fetal Imaging	Adult Cephalic							
& Other	Trans-rectal			1			┨╼┄┈╌╌╸╼╾╼╼╼╼╼┝	
	Transvaginal	·		-			<del>  · · -  </del> -	
	Trans-urethral			· · · · · · · · · · · · · · · · · · ·		· · · · · · · · · · · · · · · · · · ·		· · · · · · · · · · · · · · · · · · ·
•	Trans-esoph. (non-Card.)		· · · · ·	· ···			<u> </u>	
	Musculo-skel. (Convent.)	P	Р	P		Р	P	Р
	Musculo-skel, (Superfic.)	P	P	P		- 4	P +	P
	Intra-luminal		, <u></u>		A	<u>-</u>	<u>├───</u>	
	Other (spec.)		-				┟┈╾┈╺╋	
	Cardiac Adult						┝╾──────	
Cardiac	Cardiac Pediatric		<u> </u>				<u>+</u> +	
	Trans-esophageal (card.)						┼╍╍┊━╍╶┼	
	Other (spec.)						<u>॑</u> ╷┈╴╴╴╼╼╼┠╸	
Peripheral	Peripheral vessel	P	P	P		Р	P	Р
Vessel	Other (spec.)						<u> </u>	<u> </u>

# Intended use: Disgnostic ultrasound imaging or fluid flow analysis if the human body as follows: Clinical Application

N = new indication, P = previous indication

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

\*\*Amplitude Doppler and Harmonic Imaging.

# Additional Comments:

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

	Jerre B Chickle Post 100
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 bioney
Subscript "c":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy,
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.
(121 L'AS	E DO NOT WERE DELOW WITH A DELOS TO THE STATE

EASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number:

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices 510(k) Number \_\_\_\_

Prescription Use (Per 21 CFR 801.109)

87102960221+

From-Hitachi Medical Systems America Wepp:21 B

System:

HI VISION 900 EUP-053T Transducer:

Clinical Application			Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	M	Dwg	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthalmic	Ophthalmic									
	Fetal Abdominal									
	Intra operative (Spec.) Intra operative (Neuro.)	Pb	_Pb	РЬ		£р	РЬ	Pb		
	Laparoscopic Pediatric	;	I. 	<u> </u>		······				
	Small Organ (Spec.)									
Fetal Imaging	Neonatal Cephalic Adult Cephalic						}			
& Other	Trans-rectal Trans-vaginal									
	Trans-urethral Trans-esoph. (non-Card.)							······		
	Musculo-skel. (Convent.)									
	Musculo-skel. (Superfic.) Intra-luminal		<u> </u>							
	Other (spec.)		1							
<u> </u>	Cardiac Adult									
Cardiac	Cardiac Pediatric Trans-csophageal (card.)									
The second second	Other (spec.)		ļ	ļ						
Peripheral Vessel	Peripheral vessel Other (spec.)	. <u></u>	<u> </u>			· · · · · · · · · · · · · · · · · · ·				

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

N = ncw indication, P = previous indication

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

\*\*Amplitude Doppler and Harmonic Imaging.

### Additional Comments

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures),
Subscript c	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript d	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e"	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.
(DI TAS	TO NOT WEITE BELOW THIS I INTE-CONTINUE ON ANOTHER WAAR TO MERDED.

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED Concurrence of CDRH, Office of Device Evaluation (ODE)

> (Division Sign-Off) Division of Reproductive, Abdominal, ENT, and Radiological Devices

(0136 1 510(k) Number:

m

(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices 510(k) Number

Prescription Use (Per 21 CFR 801.109)

188-3 1-083 6 014/050 87206980661+

From-Hitachi Medical Systems America

14 90-61-000

Weyy:Z[

## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM HI VISION 900 EUP-OL334

Transducer: EUP-OL334

System:

Clinical Application		Mode of Operation								
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthalmic	Ophthalmic		1					(opec.)		
	Fetal Abdomínal									
	Intra-operative (Spec.) Intra-operative (Neuro.)									
	Laparoscopic Pediatric	P	P	P		<u> </u>	P	Р		
	Small Organ (Spec.) Neonatal Cephalic	<u> </u>				**************************************				
Fetal Imaging & Other	Adult Cephalic Trans-rectal	· · · · _						·····		
	Trans-vaginal					· · · ·				
	Trans-urethral Trans-esoph. (non-Card.)									
	Musculo-skel. (Convent.) Musculo-skel. (Superfic.)					·		· · · · · · · · · ·		
	Intra-luminal Other (spec.)							· · · · · · · · · · · · · · · · · · ·		
	Cardiac Adult									
Cardiac	Cardiac Pediatric Trans-esophageal (card.)									
	Other (spac.)					· · · · · · · · · · · · · · · · · · ·	<u> </u>			
Peripheral Vessel	Peripheral vessel Other (spec.)				· · · · ·	· · · · · · · · · · · · · · · · · · ·				

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

N = new indication, P = previous indication

\*Combination of each operating mode, B, M, PWD and Color Doppier.

\*\*Amplitude Doppler

Additional Comments

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including ampiocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
·····	(excluding neurosurgery and laparoscopic procedures).
Subscript "c"	Includes thyroid, parathyroid, breast, scrotum, penis,
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript f	Includes imaging for guidance of transvaginal biopsy.
Subscript "g"	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.
(DI EAS	SE DO NOT WRITE BELOW THIS I THE CONTINUE ON COMPUTER DUCE THE

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Division of Reproductive, Abdominal, ENT, and Radiological Devices

۳٥

510(k) Number:

(Division Sign-Off)

Division of Reproductive, Abdominal, and Badiological Devices KOCS 510(k) Number \_\_\_\_ KOCS

Prescription Use (Per 21 CFR 801.109)

T-083 P.015/020 F-891

From-Hitachi Medical Systems America

WE\$\$:21

System: Transducer:

# EUP-R54AW-19, -33

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

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

N = new indication, P = previous indication \*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler and Harmonic Imaging.

Additional Comments:

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis
Subscript "d";	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal blopsy.
Subscript "f"	Includes imaging for guidance of transvaginal biopey.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.
(PLEAS	SE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
1/0/2/10
510(k) Number: 15063518

m

(Division Sign-Off) Division of Reproductive. Abdominal, and Radiological Devices 5 Eliky Nombes

Prescription Use (Per 21 CFR 801.109)

#### DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM HI VISION 900 EUP-S50

System: Transducer:

#### **Clinical Application** Mode of Operation General Specific В Μ PWD CWD Color Combined Other\*\* (Track I only) (Tracks I & III) Doppler (Spec.) (Spec.) Ophthalmic Ophthalmic Fetal P ρ p β D Abdominal Pa Pa Ра Рa Pa Pa Pa Intra operative (Spec.) Intra-operative (Neuro.) Laparoscopic Pediatric р Ρ P Ρ Ρ P P Small Organ (Spec.) Neonatal Cephalic Fetal Imaging Adult Cephalic Ρ P P Ρ P P P & Other Trans-rectal Trans-vaginal Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.) Cardiac Adult ٢ ۲ Cardiac Cardiac Pediatric P ř r P Þ P P Trans-esophageal (card.) Other (spec.) Peripheral Peripheral vessel p P P p P P Р Vessel Other (spec.)

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

N = new indication. P = previous indication

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

\*\*Amplitude Doppler, Harmonic Imaging

Additional Comments:

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including Amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
·····	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d"	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f"	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.
(PI RAC	NE DO NOT UIDITE PET OU THIS I NE CONTRACTOR ON A STATE

O NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Division of Reproductive, Abdominal, ENT, and Radiological Devices

150 510(k) Number:

R. Lunn (Division Sign-Off)

Division of Reproductive, Abdominal, and Aradiom at Devices H063518

Prescription Use (Per 21 CFR 801.109)

1-083 6.017/020 F-891

67206960661+

From-Hitachi Medical Systems America

17

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM HI VISION 900 EUP-TC3

System: Transducer

	ical Application	Mode of Operation								
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthalmic	Ophthalmic	i		1			++			
	Fetal		1							
	Abdominal		·	1			┼───┼			
	Intra operative (Spec.)		<u> </u>	1			<u> </u>			
	Intra-operative (Neuro.)		[				† <b></b>			
	Laparoscopic		T				· · · · · · · · · · · · · · · · · · ·			
	Pediatric		1	1		······································	1			
	Small Organ (Spec.)		· · · · ·				1			
	Neonatal Cephalic						<del> </del>	·····		
Fetal Imaging	Adult Cephalic		-							
& Other	Trans-rectal									
	Trans-vaginal					······	++			
	Trans-urethral						<b>***</b>			
	Trans-esoph. (non-Card.)							·····		
	Musculo-skel (Convent.)						1			
	Musculo-skel (Superfic.)						1			
	Intra-luminal					· · · · · · · · · · · · · · · · · · ·	1			
	Other (spec.)				· · · · · · · · · · · · · · · · · · ·			· · · · · · · · · · · · · · · · · · ·		
	Cardiac Adult		1		P	<u> </u>	<u>†</u> <u>†</u>			
Cardiac	Cardiac Pediatric		[		P	···	<u>+</u>			
	Trans exophageal (card.)	••••••••					┼╾╶──┼			
	Other (spec.)						<u>+</u>			
Pcripheral	Peripheral vessel		h	<u>† − − − </u>	P		┼╾╼╾╸			
Vessel	Other (spec.) ion, P = previous indication			1			<u>†</u>	·····		

### Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows: Clinical Application Mode of Operation Γ

\*No combination modes

""No other modes

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 higher
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f"	Includes imaging for guidance of transvaginal biopsy.
Subscript "g"	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.
(PLEAS	E DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

> (Division Sign-Off) Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number:

(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices 510(k) Number

Prescription Use (Per 21 CFR 801.109)

168-4 0Z0/810 4 680-1

67206960281+

Transducer EUP-U533

System:

Clin	Mode of Operation								
Ceneral (Track I only)	Specific (Tracks I & III)	B	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)	
Ophthalmic	Ophthalmic								
· · · · · · · ·	Ophthalmic Fetal Abdominal Intra-operative (Spec.) Intra-operative (Neuro.) Laparoscopic Pediatric Small Organ (Spec.) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-rectal Trans-usethal Trans-usethal Trans-usethal Trans-scoph. (non-Card.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.)	Ph	Ph	Ph		Ph	Ph	Ph	
Cardiac	Cardiac Adult Cardiac Pediatric Trans esophageal (card.) Other (spec.)					· · · · · · · · · · · · · · · · · · ·		······	
Peripheral Vessel	Peripheral vessel Other (spec.)			· · · · · · · · · · · · · · · · · · ·					

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

N = new indication, P = previous indication

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

\*\*Amplitude Doppler and Harmonic Imaging.

Additional Comments:

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "1":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.
(PLEA	SE DO NOT WRITE RELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number

(Division Sign-Off)

Division Sign-On) Division of Reproductive, Abdominal, and Reducingual Devices S FOR) Number KOG.

Prescription Use (Per 21 CFR 801.109)

T-063 P.019/020 F-891

61330863014

From-Hitachi Medical Systems America

90-61-090

wegp:Zi

System: HI VISION 900 Transducer: EUP-V53W

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	ĊWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmi:	Ophthalmic							
	Petal   Abdominal   Intra operative (Spec.)   Intra operative (Neuro.)   Laparoscopic   Pediatric   Small Organ (Spec.)   Neonatal Cephalic   Adult Cephalic   Trans-rectal   Trans-rectal   Trans-rectal   Trans-rectal   Musculo-skel. (Convent.)   Musculo-skel. (Superfic.)   Intra-luminal   Other (spec.)	P Pe Pf	P Pe Pf	P Pe Pf		P Pe Pf	Pe Pf	P P Pe Pf
Cardiac	Cardiac Adult Cardiac Pediatric Trans-csophageal (card.) Other (spec.)							
Pcripheral Vessel	Peripheral vessel Other (spec.)							

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

N = new indication, P = previous indication

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

\*\*Amplitude Doppler, Harmonic Imaging and 3D Imaging.

Additional Comments

Subscript a	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b"	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures),
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d"	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f"	Includes imaging for guidance of transvaginal biopsy.
Subscript "g";	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.
(PLEAS	SE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH. Office of Device Evaluation (ODE)

(Division Sign-Off) Division of Reproductive, Abdominal, ENT, and Radiological Devices

351 06 510(k) Number

rÒ

(Division Sign-Off) Division of Reproductive, Abdominal, and Padiological Devices 20635-10 510(k) Number

Prescription Us: (Per 21 CFR 801.109)

1-083 P.020/020 F-891

67202960221+

Dec-19-06 System Rrom-Hendrical Systems America