

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

December 6, 2016

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

Re: K160559

Trade/Device Name: NOBLUS[™] Ultrasound Diagnostic System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, ITX Dated: October 13, 2016 Received: October 14, 2016

Dear Ms. Van Arsdale:

This letter corrects our substantially equivalent letter of October 18, 2016.

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 <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); 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

<u>http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm</u> 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

For

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

Sincerely yours,

Robert Ochs, Ph.D. Director Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.

maioano ioi oo		
510(k) Number (if known)		
K160559		
Device Name		
NOBLUS™ Ultrasound Diagnostic System		
Indications for Use (Describe)		
The Noblus™ Ultrasound Diagnostic System is intended for use		
diagnostic ultrasound evaluation of Abdominal, Cardiac, Intra-		
esophageal (Cardiac/Non-Cardiac) – Adult/Pediatric, Wound (Ceripheral vessel, Biopsy, Trans-rectal, Trans-vaginal, Musculo		
Cephalic, Endoscopy, Intra-luminal, Gynecology, Urology, and		• · · · · · · · · · · · · · · · · · · ·
copilatio, Endoscopy, inita familiai, Gynecology, Clology, and	Euparoscopie emme	п пррпошноно.
The modes of Operation of the Hitachi Noblus™ Ultrasound Di	iagnostic System are	B mode, M mode, PW mode (Pulse
Wave Doppler), CW mode (Continuous Wave Doppler), Color		
TDI (Tissue Doppler Imaging), 3D Imaging, 4D Imaging, and F	Real Time Tissue Elas	stography.
Type of Use (Select one or both, as applicable)		
Prescription Use (Part 21 CFR 801 Subpart D)	Over-The-Counter	er Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov

"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."

System:

Noblus

Transducer:

All connectable probes

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

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

N = new indication. P = previously cleared in K142368

Additional Comments:

. raditional commi						
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":	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 imaging for guidance of trans-vaginal biopsy.					
Subscript "g":	For Adult and Pediatric patients.					
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds					

Prescription Use Only (per 21 CFR 801.109)

(PLEASE DO NO 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:	

^{*}Combination of each operating mode, B, M, PWD, and Color Doppler; B/B, B/M, B/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

^{**}Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging, 3D Imaging, 4D Imaging, Omni Directional M mode, Wide View, Contrast Imaging, Real Time Tissue Elastography

System:

Transducer:

C22I

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

Clinical Application			Mode of Operation							
General	Specific	В	М	PWD	CWD	Color	Combined*	Other**		
(Track I only)	(Tracks I & III)	ь	141	TWD	CWB	Doppler	(Spec.)	(Spec.)		
Ophthalmic	Ophthalmic									
	Fetal									
	Abdominal	P	P	P		P	P	P		
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb	Pb	Pb		
	Intra-operative (Neuro.)									
	Laparoscopic									
	Pediatric									
	Small Organ (Spec.)									
	Neonatal Cephalic									
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.) - Wound									
	Other (spec.) - Gynecological									
	Other (spec.) - Endoscopy									
	Other (spec.) -									
	Cardiac Adult									
Cardiac	Cardiac Pediatric									
	Trans-esophageal (card.)									
	Other (spec.)									
Peripheral	Peripheral vessel									
Vessel	Other (spec.) -									
	P = previously cleared in K142368									
ombination of eac	ch operating mode, B, M, PWD, and	Color Doppl	ler; B/B, B/N	1, B/PW, B/C	W, CFM-B/C	W, CFM-B/CFM	-B, CFM-B/CFM-N	1,		
	CFM-B/PW									
Amplitude Dopple	er (Color Flow Angiography), 3D Im-	aging, Wide	View, Cont	rast Imaging						

Additional	Comments

ridditional Commi	ionts.							
Subscript "a":	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 imaging for guidance of trans-vaginal biopsy.							
Subscript "g":	For Adult and Pediatric patients.							
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds							

Prescription Use Only (per 21 CFR 801.109)

(Division Sign – Off)	
Division of Radiological Health	
Office of In Vitro Diagnostic and Radiological Health	
510(k) Number:	

System:

Noblus

Transducer: C22K
Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application	gnostic ultrasound imaging or ii	T TOW UNIO	you it the i	aman oouj a		Operation		
General	Specific		100,000			Color	Combined*	Other**
(Track I only)	(Tracks I & III)	В	М	PWD	CWD	Doppler	(Spec.)	(Spec.)
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
,	Intra-operative (Spec.)	Pb	Pb	Pb		Pb	Pb	Pb
	Intra-operative (Neuro.)					_		
	Laparoscopic							
	Pediatric					_		
	Small Organ (Spec.)							
	Neonatal Cephalic					1		
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.) - Wound							
	Other (spec.) - Gynecological							
	Other (spec.) - Endoscopy	_						
	Other (spec.) -							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.) -							
N = new indication. *Combination of each	P = previously cleared in K142368 th operating mode, B, M, PWD, and CFM-B/PW	l Color Dopple	er; B/B, B/M	, B/PW, B/CW	V, CFM-B/CW	, CFM-B/CFM-I	3, CFM-B/CFM-M,	
	er (Color Flow Angiography), 3D Ir	maging, Wide	View, Contra	st Imaging				
Additional Comment						Carladian and		
Subscript "a":	Includes imaging for guidance of							
Subscript "b":	Includes imaging of organs and st			rgery (excludir	ig neurosurgei	ry and iaparoscop	ne procedures).	
Subscript "c":	Includes thyroid, parathyroid, brea				CL:			
Subscript "d":	Includes thyroid, parathyroid, brea			ging for guidar	nce of biopsy.			
Subscript "e":	Includes imaging for guidance of t							
Subscript "f":	Includes imaging for guidance of t	rans-vaginal b	iopsy.					

Prescription Use Only (per 21 CFR 801.109)

Subscript "g":

Subscript "h":

For Adult and Pediatric patients.

Includes imaging for Cavernous/Non-Cavernous wounds

(Division Sign – Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k) Number:

Noblus C22P

Transducer:

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

inical Application	1	Mode of Operation						
General	В	М	PWD	CWD	Color	Combined*	Other**	
(Track I only)	(Tracks I & III)	В	M	PWD	CWD	Doppler	(Spec.)	(Spec.)
Ophthalmic	Ophthalmic							
	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							
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.) - Wound							
	Other (spec.) - Gynecological						_	
	Other (spec.) - Endoscopy							
	Other (spec.) -							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.) -							
	P = previously cleared in K142368		and the contract					
ombination of eac	ch operating mode, B, M, PWD, and	Color Doppl	ler; B/B, B/N	1, B/PW, B/C	W, CFM-B/C	W, CFM-B/CFM	-B, CFM-B/CFM-N	И,
	er (Color Flow Angiography), 3D Im		View Contr	act Imagina				

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.	
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Subscript "f":	Includes imaging for guidance of trans-vaginal biopsy.	
Subscript "g":	For Adult and Pediatric patients.	
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds	

Prescription Use Only (per 21 CFR 801.109)

(Division Sign – Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k) Number:

System:

Noblus

Transducer:

C22T

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

cal Application					111000 01	Operation Color	Combined*	Other**
General	Specific	В	M	PWD	CWD		(Spec.)	(Spec.)
(Track I only)	(Tracks I & III)					Doppler	(Spec.)	(Spec.)
Ophthalmic	Ophthalmic							
	Fetal					P	P	P
	Abdominal	P	P	P			Pb	Pb
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb	PO	PO
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
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.) - Wound							
	Other (spec.) - Gynecological						_	
	Other (spec.) - Endoscopy							
	Other (spec.) -			1				
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.) -							

^{**}Amplitude Doppler (Color Flow Angiography), 3D Imaging, Wide View, 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 imaging for guidance of trans-vaginal biopsy.
Subscript "g":	For Adult and Pediatric patients.
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (per 21 CFR 801.109)

(PLEASE DO NO 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:	
.,	

Mode of Operation

Doppler

Pa

P

Pd

CWD

Combined*

(Spec.)

P

Pa

Pd

Other**

(Spec.)

P

Pa

Pd

System:	Noblus			
Transducer:	C25			
Intended use: Diag	nostic ultrasound imaging or fluid f	low analysis if t	he human bo	dy as follo
Clinical Application				
General (Track I only)	Specific (Tracks I & III)	В	М	PWD
Ophthalmic	Ophthalmic			10
	Fetal	P	P	P
	Abdominal	Pa	Pa	Pa
	Intra-operative (Spec.)			
	Intra-operative (Neuro.)			
	Laparoscopic			
	Pediatric	P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd

Neonatal Cephalic

Adult Cephalic

Trans-rectal
Trans-vaginal
Trans-surethral
Trans-esoph. (non-Card.)
Musculo-skel. (Convent.)
Musculo-skel. (Superfic.)
Intra-luminal
Other (spec.) - Wound
Other (spec.) - Gynecological
Other (spec.) - Endoscopy
Other (spec.) - Cardiac Adult

Vessel Other (spec.)
N = new indication. P = previously cleared in K142368

Cardiac Pediatric Trans-esophageal (card.) Other (spec.)

Peripheral vessel

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

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

Additional Comments:

Cardiac

Peripheral

Fetal Imaging

& Other

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 imaging for guidance of trans-vaginal biopsy.
Subscript "g":	For Adult and Pediatric patients.
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (per 21 CFR 801.109)

(PLEASE DO NO 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:_____

System: Transducer: C251

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

linical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic			1802				
•	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							
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.) - Wound						1	
	Other (spec.) - Gynecological							_
	Other (spec.) - Endoscopy							
	Other (spec.) -							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)				_			
Peripheral	Peripheral vessel							
Vessel	Other (spec.) - P = previously cleared in K142368							

Additional Comments:

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
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Prescription Use Only (per 21 CFR 801.109)

 (Division Sign – Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k) Number:

^{**}Amplitude Doppler (Color Flow Angiography), 3D Imaging, Omni Directional M mode, Wide View, Contrast Imaging, Real Time Tissue Elastography

System:

Transducer:

Noblus C35

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

linical Application	1	Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
	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							
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.) - Wound							
	Other (spec.) - Gynecological							
	Other (spec.) - Endoscopy							
	Other (spec.) -							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.) -							

N = new indication. P = previously cleared in K142368

Additional Comments:

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
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Subscript "f":	Includes imaging for guidance of trans-vaginal biopsy.
Subscript "g":	For Adult and Pediatric patients.
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (per 21 CFR 801.109)

(PLEASE DO NO 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:_

^{*}Combination of each operating mode, B, M, PWD, and Color Doppler; B/B, B/M, B/PW, B/CW, CFM-B/CW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW,

^{**}Amplitude Doppler (Color Flow Angiography), 3D Imaging, Omni Directional M mode, Wide View,

System:

Noblus C41

Transducer:

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

linical Application	1	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	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							
Fetal Imaging	Adult Cephalic							
& Other	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.) - Wound							
	Other (spec.) - Gynecological							
	Other (spec.) - Endoscopy							
	Other (spec.) -							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel	P	P	P		P	P	P
Vessel	Other (spec.) - P = previously cleared in K142368							

Additional Comments:

ridditional Commi	TOTAL CONTROL OF THE PROPERTY	
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 imaging for guidance of trans-vaginal biopsy.	
Subscript "g":	For Adult and Pediatric patients.	
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds	

Prescription Use Only (per 21 CFR 801.109)

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> (Division Sign - Off) Division of Radiological Health Office of In Vitro Diagnostic and Radiological Health 510(k) Number:_

N = new indication. P = previously cleared in K142368
*Combination of each operating mode, B, M, PWD, and Color Doppler; B/B, B/M, B/PW, B/CW, CFM-B/CW, CFM-B/CFM-B, CFM-B/CFM-M,

^{**}Amplitude Doppler (Color Flow Angiography), 3D Imaging, Wide View,

System:

Noblus C41B

Transducer:

stic ultrasound imaging or fluid flow analysis if the human body as follows:

nical Application				Mode of Operation Color Combined* Other				
General	Specific	В	М	PWD	CWD	Color	E-14/2013-1-11-11-11-11	Other**
(Track I only)	(Tracks I & III)					Doppler	(Spec.)	(Spec.)
Ophthalmic	Ophthalmic							
	Fetal	P	P	P		P	P	P
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic				_			
Fetal Imaging	Adult Cephalic					_		
& Other	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.) - Wound							
	Other (spec.) - Gynecological				_	_		
	Other (spec.) - Endoscopy							
	Other (spec.) -							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.) -							
new indication. nbination of ead I-B/PW	P = previously cleared in K142368 ch operating mode, B, M, PWD, and	Color Doppi	ler; B/B, B/N	и, в/PW, в/С	W, CFM-B/C	W, CFM-B/CFM	I-B, CFM-B/CFM-N	1,

Additional Commit		
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 imaging for guidance of trans-vaginal biopsy.	
Subscript "g":	For Adult and Pediatric patients.	
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds	

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:_

^{**}Amplitude Doppler (Color Flow Angiography), 3D Imaging, Wide View, Contrast Imaging, Real Time Tissue Elastography

Noblus

Transducer:

C41L47RP

ical Application				Mode of Operation Color Combined* Other				Othor**
General	Specific	В	M	PWD	CWD	10 5525		(Spec.)
(Track I only)	(Tracks I & III)					Doppler	(Spec.)	(Spec.)
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
Fetal Imaging	Adult Cephalic	_						
& Other	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.) - Wound			_				
	Other (spec.) - Gynecological							
	Other (spec.) - Endoscopy							
	Other (spec.) -					_		
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.) -							
new indication. nbination of ea I-B/PW	P = previously cleared in K142368 ch operating mode, B, M, PWD, and	Color Dopp	ler; B/B, B/N	M, B/PW, B/C	W, CFM-B/C	W, CFM-B/CFM	I-B, CFM-B/CFM-N	Л,

Additional Comments:

ridditional Commit	
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 imaging for guidance of trans-vaginal biopsy.
Subscript "g":	For Adult and Pediatric patients.
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (per 21 CFR 801.109)

(Division Sign – Off)	
Division of Radiological Health	
Office of In Vitro Diagnostic and Radiological Health	
510(k) Number:	

System:

Noblus

Transducer: C41V

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

Clinical Application	nostic ultrasound imaging or fluid fl	Mode of Operation						
General	Specific	Ъ	М	PWD	CWD	Color	Combined*	Other**
(Track I only)	(Tracks I & III)	В	IVI	PWD	CWD	Doppler	(Spec.)	(Spec.)
Ophthalmic	Ophthalmic							
	Fetal	P	P	P		P	P	P
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic				-			
Fetal Imaging	Adult Cephalic							
& Other	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.) - Wound							
	Other (spec.) - Gynecological	P	P	P		P	P	P
	Other (spec.) - Endoscopy							
	Other (spec.) -							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.) -					_		
	P = previously cleared in K142368 ch operating mode, B, M, PWD, and		er; B/B, B/N	л, B/PW, B/C	W, CFM-B/C	W, CFM-B/CFM	I-B, CFM-B/CFM-N	м,
FM-B/PW								
'Amplitude Doppl	er (Color Flow Angiography), 3D Ir	naging, Wide	View, Contr	ast Imaging, F	Real Time Tiss	sue Elastography		
dditional Commer								
	Includes imposing for quidence of		·	1 1	1	o (including om	aio contocia)	

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 imaging for guidance of trans-vaginal biopsy.
Subscript "g":	For Adult and Pediatric patients.
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (per 21 CFR 801.109)

(Division Sign – Off)	
Division of Radiological Health	
Office of In Vitro Diagnostic and Radiological Health	
510(k) Number:	

System:

Transducer: C41V1
Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Citack I only Citacks I & III Doppler CWD Doppler CSp			Operation	Mode of					nical Application
Ophthalmic Ophthalmic Petal P P P P P P P P P P P P P P P P P P	seconder,	Combined* (Spec.)	(4, 4, 6, 6, 6, 6,	CWD	PWD	М	В	354 A 1555 A	3537200000000
Fetal									
Abdominal Intra-operative (Spec.) Intra-operative (Neuro.) Intra-op	P	P	P		P	P	P		-
Intra-operative (Spec.) Intra-operative (Neuro.) Intra-operative (Neu									
Intra-operative (Neuro.) Laparoscopic Pediatric Small Organ (Spec.) Neonatal Cephalic Pe Pe Pe Pe Pe Pe Pe Pe Pe Pf									
Pediatric Small Organ (Spec.) Neonatal Cephalic Adult Cephalic Pe Pe Pe Pe Pe Pe Pe Pf									
Small Organ (Spec.) Neonatal Cephalic Adult Cephalic Pe									
Neonatal Cephalic								Pediatric	
Adult Cephalic Trans-rectal Pe Pe Pe Pe Pe Pe Pe P								Small Organ (Spec.)	
& Other								Neonatal Cephalic	
& Other								Adult Cephalic	Fetal Imaging
Trans-vaginal Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.) - Wound Other (spec.) - Gynecological P P P P P P Other (spec.) - Endoscopy Other (spec.) - Cardiac Adult		Pe	Pe		Pe	Pe	Pe	Trans-rectal	
Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.) - Wound Other (spec.) - Gynecological P P P P P Other (spec.) - Endoscopy Other (spec.) - Cardiac Adult Car	f Pf	Pf	Pf		Pf	Pf	Pf	Trans-vaginal	
Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.) - Wound Other (spec.) - Gynecological P P P P Other (spec.) - Endoscopy Other (spec.) - Cardiac Adult		_						Trans-urethral	
Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.) - Wound Other (spec.) - Gynecological P P P P Other (spec.) - Endoscopy Other (spec.) - Cardiac Adult								Trans-esoph. (non-Card.)	
Intra-luminal								Musculo-skel. (Convent.)	
Other (spec.) - Wound P								Musculo-skel. (Superfic.)	
Other (spec.) - Gynecological P P P P P P P P P P P P P P P P P P P								Intra-luminal	
Other (spec.) - Gynecological Other (spec.) - Endoscopy Other (spec.) - Cardiac Adult								Other (spec.) - Wound	
Other (spec.) - Cardiac Adult	P	P	P	_	P	P	P	Other (spec.) - Gynecological	
Cardiac Adult								Other (spec.) - Endoscopy	
								Other (spec.) -	
								Cardiac Adult	
Cardiac Cardiac Pediatric								Cardiac Pediatric	Cardiac
Trans-esophageal (card.)								Trans-esophageal (card.)	
Other (spec.)								Other (spec.)	
Peripheral Peripheral vessel								Peripheral vessel	Peripheral
Vessel Other (spec.) -				_					
new indication. P = previously cleared in K142368								P = previously cleared in K142368	new indication.
ombination of each operating mode, B, M, PWD, and Color Doppler; B/B, B/M, B/PW, B/CW, CFM-B/CW, CFM-B/CFM-B, CFM-B/PW	-B/CFM-M,								M-B/PW
amplitude Doppler (Color Flow Angiography), 3D Imaging, Wide View, Contrast Imaging, Real Time Tissue Elastography			sue Elastography	eal Time Tiss	ast Imaging, R	View, Contra	naging, Wide	r (Color Flow Angiography), 3D Im	mplitude Dopple

Additional Comments:

riddittonal Commi	ionis.
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 imaging for guidance of trans-vaginal biopsy.
Subscript "g":	For Adult and Pediatric patients.
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (per 21 CFR 801.109)

(Division Sign - Off)	
Division of Radiological Health	
Office of In Vitro Diagnostic and Radiological Health	
510(k) Number:	

System:

Noblus

Transducer:

C42 Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

linical Application	nostic ultrasound imaging of fluid fi	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.)	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		
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.) - Wound									
	Other (spec.) - Gynecological									
	Other (spec.) - Endoscopy									
	Other (spec.) -									
	Cardiac Adult									
Cardiac	Cardiac Pediatric									
	Trans-esophageal (card.)									
	Other (spec.)									
Peripheral	Peripheral vessel	P	P	P		P	P	P		
Vessel	Other (spec.) -									

N = new indication. P = previously cleared in K142368

Additional Comments

Additional Comm	icitis.	
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 imaging for guidance of trans-vaginal biopsy.	
Subscript "g":	For Adult and Pediatric patients.	
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds	

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^{*}Combination of each operating mode, B, M, PWD, and Color Doppler; B/B, B/M, B/PW, B/CW, CFM-B/CW, CFM-B/CFM-B, CFM-B/CFM-M,

^{**}Amplitude Doppler (Color Flow Angiography), 3D Imaging, Wide View, Real Time Tissue Elastography

System: C42K Transducer:

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

nical 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									
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb	Pb	Pb		
	Intra-operative (Neuro.)									
	Laparoscopic									
	Pediatric									
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd		
	Neonatal Cephalic									
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.) - Wound									
	Other (spec.) - Gynecological									
	Other (spec.) - Endoscopy									
	Other (spec.) -									
	Cardiac Adult									
Cardiac	Cardiac Pediatric									
	Trans-esophageal (card.)									
	Other (spec.)									
Peripheral	Peripheral vessel									
Vessel	Other (spec.) -		1							

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 imaging for guidance of trans-vaginal biopsy.
Subscript "g":	For Adult and Pediatric patients.
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds

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(Division Sign - Off) Division of Radiological Health Office of In Vitro Diagnostic and Radiological Health 510(k) Number:_____

^{*}Combination of each operating mode, B, M, PWD, and Color Doppler; B/B, B/M, B/PW, B/CW, CFM-B/CW, CFM-B/CFM-B, CFM-B/CFM-M,

^{**}Amplitude Doppler (Color Flow Angiography), 3D Imaging, Wide View

System: Noblus Transducer: C42T

ostic ultrasound imaging or fluid flow analysis if the human body as follows:

nical Application	inical Application		Mode of Operation Color Combined* Other**								
General	Specific	В	М	PWD	CWD	Color	Combined*				
(Track I only)	(Tracks I & III)					Doppler	(Spec.)	(Spec.)			
Ophthalmic	Ophthalmic										
	Fetal										
	Abdominal										
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb	Pb	Pb			
	Intra-operative (Neuro.)			_		16					
	Laparoscopic										
	Pediatric				_						
	Small Organ (Spec.)										
	Neonatal Cephalic										
Fetal Imaging	Adult Cephalic										
& Other	Trans-rectal							i i			
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)				_						
	Musculo-skel. (Convent.)										
	Musculo-skel. (Superfic.)										
	Intra-luminal										
	Other (spec.) - Wound			<u> </u>							
	Other (spec.) - Gynecological										
	Other (spec.) - Endoscopy										
	Other (spec.) -										
	Cardiac Adult					_					
Cardiac	Cardiac Pediatric										
	Trans-esophageal (card.)										
	Other (spec.)										
Peripheral	Peripheral vessel										
Vessel	Other (spec.) -										
new indication. mbination of each	P = previously cleared in K142368 ch operating mode, B, M, PWD, and	Color Dopp	ler; B/B, B/N	м, B/PW, B/С	W, CFM-B/C	W, CFM-B/CFM	I-B, CFM-B/CFM-N	1,			

Additional Comments:

ridditional Commi	onto.
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 imaging for guidance of trans-vaginal biopsy.
Subscript "g":	For Adult and Pediatric patients.
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (per 21 CFR 801.109)

(PLEASE DO NO 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:_____

System:

Noblus CC41R

Transducer:

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

nical Application		Mode of Operation								
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthalmic	Ophthalmic									
	Fetal	P	P	P		P	Р ,	P		
	Abdominal									
	Intra-operative (Spec.)									
	Intra-operative (Neuro.)									
	Laparoscopic					_				
	Pediatric									
	Small Organ (Spec.)									
	Neonatal Cephalic									
Fetal Imaging	Adult Cephalic									
& Other	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.) - Wound									
	Other (spec.) - Gynecological									
	Other (spec.) - Endoscopy									
	Other (spec.) -									
	Cardiac Adult									
Cardiac	Cardiac Pediatric									
	Trans-esophageal (card.)									
	Other (spec.)									
Peripheral	Peripheral vessel									
Vessel	Other (spec.) -									

^{*}Combination of each operating mode, B, M, PWD, and Color Doppler; B/B, B/M, B/PW, B/CW, CFM-B/CW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW

Additional Comments:

Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Includes thyroid, parathyroid, breast, scrotum, penis.
Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Includes imaging for guidance of trans-rectal biopsy.
Includes imaging for guidance of trans-vaginal biopsy.
For Adult and Pediatric patients.
Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (per 21 CFR 801.109)

(Division Sign – Off)	
Division of Radiological Health	
Office of In Vitro Diagnostic and Radiological Health	
510(k) Number:	

^{**}Amplitude Doppler (Color Flow Angiography), 3D Imaging, Contrast Imaging, Real Time Tissue Elastography

System:

Noblus

Transducer: EUP-B512

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

linical Application	1	Mode of Operation								
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthalmic	Ophthalmic									
	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									
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.) - Wound									
	Other (spec.) - Gynecological									
	Other (spec.) - Endoscopy									
	Other (spec.) -									
	Cardiac Adult									
Cardiac	Cardiac Pediatric									
	Trans-esophageal (card.)									
	Other (spec.)									
Peripheral	Peripheral vessel									
Vessel	Other (spec.) -									

N = new indication. P = previously cleared in K142368

Additional Comments:

raditional commi	19 III O	
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 imaging for guidance of trans-vaginal biopsy.	
Subscript "g":	For Adult and Pediatric patients.	
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds	

Prescription Use Only (per 21 CFR 801.109)

(PLEASE DO NO 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:	

^{*}Combination of each operating mode, B, M, PWD, and Color Doppler; B/B, B/M, B/PW, B/CW, CFM-B/CW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW, CFM-B/PW

^{**}Amplitude Doppler (Color Flow Angiography), 3D Imaging, Wide View, Contrast Imaging

 System:
 Noblus

 Transducer:
 EUP-B715

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

Clinical Application	Mode of Operation								
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)	
Ophthalmic	Ophthalmic								
	Fetal	P	P	P	7.00	P	P	P	
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa	
	Intra-operative (Spec.)					_			
	Intra-operative (Neuro.)								
	Laparoscopic								
	Pediatric								
	Small Organ (Spec.)								
	Neonatal Cephalic								
Fetal Imaging	Adult Cephalic								
& Other	Trans-rectal								
	Trans-vaginal							- 1	
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic.)								
	Intra-luminal								
	Other (spec.) - Wound								
	Other (spec.) - Gynecological								
	Other (spec.) - Endoscopy								
	Other (spec.) -								
	Cardiac Adult								
Cardiac	Cardiac Pediatric								
	Trans-esophageal (card.)								
	Other (spec.)								
Peripheral	Peripheral vessel								
Vessel	Other (spec.) -								

N = new indication. P = previously cleared in K142368

Additional Comments:

Additional Commi	Citis.	
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 imaging for guidance of trans-vaginal biopsy.	
Subscript "g":	For Adult and Pediatric patients.	
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds	

Prescription Use Only (per 21 CFR 801.109)

(PLEASE DO NO 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:______

^{*}Combination of each operating mode, B, M, PWD, and Color Doppler; B/B, B/M, B/PW, B/CW, CFM-B/CW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW

CFM-B/PW

**Amplitude Doppler (Color Flow Angiography), 3D Imaging, Wide View, Contrast Imaging

System:

Noblus

EUP-C715 Transducer:

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

ical 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	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									
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.) - Wound									
	Other (spec.) - Gynecological									
	Other (spec.) - Endoscopy									
	Other (spec.) -									
á	Cardiac Adult									
Cardiac	Cardiac Pediatric									
	Trans-esophageal (card.)									
	Other (spec.)									
Peripheral	Peripheral vessel									
Vessel	Other (spec.) -									

Additional Comments:

Additional Commi	Citts.	
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 imaging for guidance of trans-vaginal biopsy.	
Subscript "g":	For Adult and Pediatric patients.	
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds	

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:	

^{*}Combination of each operating mode, B, M, PWD, and Color Doppler; B/B, B/M, B/PW, B/CW, CFM-B/CW, CFM-B/CFM-B, CFM-B/CFM-M,

^{**}Amplitude Doppler (Color Flow Angiography), 3D Imaging, Omni Directional M mode, Wide View, Contrast Imaging, Real Time Tissue Elastography

System:

Noblus

Transducer:

EUP-CC531S

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

Clinical Application	nostic unrasound imaging of ridid n	Mode of Operation								
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthalmic	Ophthalmic									
	Fetal	P	P	P		P	P	P		
	Abdominal									
	Intra-operative (Spec.)									
	Intra-operative (Neuro.)									
	Laparoscopic									
	Pediatric				_					
	Small Organ (Spec.)									
	Neonatal Cephalic									
Fetal Imaging	Adult Cephalic									
& Other	Trans-rectal	Pe	Pe	Pe		Pe	Pe	Pe		
ч	Trans-vaginal	Pf	Pf	Pf		Pf	Pf	Pf		
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skel. (Convent.)									
	Musculo-skel. (Superfic.)									
	Intra-luminal									
	Other (spec.) - Wound									
	Other (spec.) - Gynecological									
	Other (spec.) - Endoscopy									
	Other (spec.) -									
	Cardiac Adult									
Cardiac	Cardiac Pediatric									
	Trans-esophageal (card.)									
	Other (spec.)									
Peripheral	Peripheral vessel									
Vessel	Other (spec.) - P = previously cleared in K142368									

N = new indication. P = previously cleared in K142368

Additional Comments:

Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).	
Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).	
Includes thyroid, parathyroid, breast, scrotum, penis.	
Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.	
Includes imaging for guidance of trans-rectal biopsy.	
Includes imaging for guidance of trans-vaginal biopsy.	
For Adult and Pediatric patients.	
Includes imaging for Cavernous/Non-Cavernous wounds	
-	Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures). Includes thyroid, parathyroid, breast, scrotum, penis. Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy. Includes imaging for guidance of trans-rectal biopsy. Includes imaging for guidance of trans-vaginal biopsy. For Adult 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:______

^{*}Combination of each operating mode, B, M, PWD, and Color Doppler; B/B, B/M, B/PW, B/CW, CFM-B/CW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW

^{**}Amplitude Doppler (Color Flow Angiography), 3D Imaging, Contrast Imaging, Real Time Tissue Elastography

System:

Noblus

Transducer:

EUP-L53L

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

linical 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						F	
	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							
Fetal Imaging	Adult Cephalic							
& Other	Trans-rectal						1	
	Trans-vaginal					1		
	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.) - Wound							
	Other (spec.) - Gynecological			,	_			
	Other (spec.) - Endoscopy							
	Other (spec.) -							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel	P	P	P		P	P	P
Vessel	Other (spec.) - P = previously cleared in K142368				_			

Additional Comments:

ridditional Commi	onto.
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 imaging for guidance of trans-vaginal biopsy.
Subscript "g":	For Adult and Pediatric patients.
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds

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:	

^{*}Combination of each operating mode, B, M, PWD, and Color Doppler; B/B, B/M, B/PW, B/CW, CFM-B/CW, CFM-B/CFM-B, CFM-B/CFM-M,

^{**}Amplitude Doppler (Color Flow Angiography), 3D Imaging, Wide View, Real Time Tissue Elastography

System:

Noblus

Transducer: EUP-L74M

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

linical 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	P	P		P	P	P	
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd	
	Neonatal Cephalic								
Fetal Imaging	Adult Cephalic								
& Other	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.) - Wound								
	Other (spec.) - Gynecological		•						
	Other (spec.) - Endoscopy								
	Other (spec.) -								
	Cardiac Adult								
Cardiac	Cardiac Pediatric								
	Trans-esophageal (card.)								
	Other (spec.)								
Peripheral	Peripheral vessel	P	P	P		P	P	P	
Vessel	Other (spec.) -								

N = new indication. P = previously cleared in K142368

Additional Comments:

Additional Comm	Citts.
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 imaging for guidance of trans-vaginal biopsy.
Subscript "g":	For Adult and Pediatric patients.
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (per 21 CFR 801.109)

(PLEASE DO NO 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:____

^{*}Combination of each operating mode, B, M, PWD, and Color Doppler; B/B, B/M, B/PW, B/CW, CFM-B/CW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW

^{**}Amplitude Doppler (Color Flow Angiography), 3D Imaging, Omni Directional M mode, Wide View, Contrast Imaging, Real Time Tissue Elastography

System: Noblus Transducer: EUP-O53T

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

nical Application	1				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							
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb	Pb	Pb
	Intra-operative (Neuro.)							
	Laparoscopic	_						
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
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.) - Wound					_		
	Other (spec.) - Gynecological							
	Other (spec.) - Endoscopy							
	Other (spec.) -							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.) - P = previously cleared in K142368							

Additional Comments:

Additional Collin	icits.	
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 imaging for guidance of trans-vaginal biopsy.	
Subscript "g":	For Adult and Pediatric patients.	
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds	

Prescription Use Only (per 21 CFR 801.109)

(PLEASE DO NO 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:_

^{**}Amplitude Doppler (Color Flow Angiography), 3D Imaging, Wide View, Contrast Imaging, Real Time Tissue Elastography

System:

Noblus

Transducer:

EUP-O54J

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

Clinical Application		Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)	
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal								
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb	Pb	Pb	
	Intra-operative (Neuro.)								
	Laparoscopic								
	Pediatric								
	Small Organ (Spec.)								
	Neonatal Cephalic								
Fetal Imaging	Adult Cephalic								
& Other	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.) - Wound								
	Other (spec.) - Gynecological								
	Other (spec.) - Endoscopy								
	Other (spec.) -								
	Cardiac Adult								
Cardiac	Cardiac Pediatric								
	Trans-esophageal (card.)								
	Other (spec.)								
Peripheral	Peripheral vessel	P	P	P		P	P	P	
Vessel	Other (spec.) -								

Additional Comments:

ridditional Commi		
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 imaging for guidance of trans-vaginal biopsy.	
Subscript "g":	For Adult and Pediatric patients.	
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds	

Prescription Use Only (per 21 CFR 801.109)

(Division Sign – Off)	
Division of Radiological Health	
Office of In Vitro Diagnostic and Radiological Health	
510(k) Number:	

N = new indication. P = previously cleared in K142368
*Combination of each operating mode, B, M, PWD, and Color Doppler; B/B, B/M, B/PW, B/CW, CFM-B/CW, CFM-B/CFM-B, CFM-B/CFM-M,

^{**}Amplitude Doppler (Color Flow Angiography), 3D Imaging, Omni Directional M mode, Wide View, Real Time Tissue Elastography

System:

Transducer:

Noblus EUP-O732T

stic ultrasound imaging or fluid flow analysis if the human body as follows:

ical Application	Mode of Operation Color Combined* Other							
General	Specific	В	М	PWD	CWD		109019000000000000000000000000000000000	200000000000000000000000000000000000000
(Track I only)	(Tracks I & III)					Doppler	(Spec.)	(Spec.)
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal							
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb	Pb	Pb
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
Fetal Imaging	Adult Cephalic							
& Other	Trans-rectal							
	Trans-vaginal							
	Trans-urethral	- 1						
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal				_			
	Other (spec.) - Wound							
	Other (spec.) - Gynecological							
	Other (spec.) - Endoscopy							
	Other (spec.) -							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.) -							

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 imaging for guidance of trans-vaginal biopsy.
Subscript "g":	For Adult and Pediatric patients.
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (per 21 CFR 801.109)

(Division Sign – Off)	
Division of Radiological Health	
Office of In Vitro Diagnostic and Radiological Health	
510(k) Number:	

System:

Noblus

Transducer:

EUP-OL334

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

linical Application		Mode of Operation							
General	Specific	В	М	PWD	CWD	Color	Combined*	Other**	
(Track I only)	(Tracks I & III)					Doppler	(Spec.)	(Spec.)	
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal								
	Intra-operative (Spec.)								
	Intra-operative (Neuro.)								
	Laparoscopic	P	P	P		P	P	P	
	Pediatric								
	Small Organ (Spec.)						_		
	Neonatal Cephalic								
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.) - Wound								
	Other (spec.) - Gynecological								
	Other (spec.) - Endoscopy								
	Other (spec.) -								
	Cardiac Adult								
Cardiac	Cardiac Pediatric								
	Trans-esophageal (card.)								
	Other (spec.)								
Peripheral	Peripheral vessel								
Vessel	Other (spec.) -				4				

CFM-B/PW

Additional Comments:

ridditional Commi							
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 imaging for guidance of trans-vaginal biopsy.						
Subscript "g":	For Adult and Pediatric patients.						
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds						

Prescription Use Only (per 21 CFR 801.109)

(Division Sign – Off)	
Division of Radiological Health	
Office of In Vitro Diagnostic and Radiological Health	
510(k) Number:	

^{**}Amplitude Doppler (Color Flow Angiography), 3D Imaging, Wide View, Contrast Imaging, Real Time Tissue Elastography

System:

EUP-R54AW-19, -33 Transducer:

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

nical Application	n				Mode of	Operation		
General	Specific	В	М	PWD	CWD	Color	Combined*	Other**
(Track I only)	(Tracks I & III)	Ь	IVI.	1 112	0.1.5	Doppler	(Spec.)	(Spec.)
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
Fetal Imaging	Adult Cephalic			_				
& Other	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.) - Wound				_			
	Other (spec.) - Gynecological							
	Other (spec.) - Endoscopy							
	Other (spec.) -							
	Cardiac Adult							
Cardiac	Cardiac Pediatric		_					
	Trans-esophageal (card.)					*		
	Other (spec.)							
Peripheral	Peripheral vessel				_			
Vessel	Other (spec.) -							
new indication. ombination of ea M-B/PW	P = previously cleared in K142368 ch operating mode, B, M, PWD, and	d Color Dopp	ler; B/B, B/N	л, B/PW, B/C	W, CFM-B/C	W, CFM-B/CFM	I-B, CFM-B/CFM-N	Л,
amplitude Doppl	ler (Color Flow Angiography), 3D In	maging, Real	Гime Tissue	Elastography				

Additional	Comments
Auditional	Commicing

ridditional Commi							
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 imaging for guidance of trans-vaginal biopsy.						
Subscript "g":	For Adult and Pediatric patients.						
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds						

Prescription Use Only (per 21 CFR 801.109)

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(Division Sign – Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k) Number:____

System: Noblus
Transducer: L34

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

Clinical Application		Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	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	P	P		P	P	P	
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd	
	Neonatal Cephalic								
Fetal Imaging	Adult Cephalic								
& Other	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.) - Wound	-							
	Other (spec.) - Gynecological								
	Other (spec.) - Endoscopy								
	Other (spec.) -								
	Cardiac Adult					1			
Cardiac	Cardiac Pediatric								
	Trans-esophageal (card.)								
	Other (spec.)								
Peripheral	Peripheral vessel	P	P	P	_	P	P	P	
Vessel	Other (spec.) -								

N =new indication. P =previously cleared in K142368

Additional Comments:

Additional Contin		
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 imaging for guidance of trans-vaginal biopsy.	
Subscript "g":	For Adult and Pediatric patients.	
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds	

Prescription Use Only (per 21 CFR 801.109)

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Office of In Vitro Diagnostic and Radiological Health
510(k) Number:_____

^{*}Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, B/CW, CFM-B/CW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/DW

^{**}Amplitude Doppler (Color Flow Angiography), 3D Imaging, Omni Directional M mode, Wide View, Contrast Imaging, Real Time Tissue Elastography

System:

Transducer:

L43K Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application					Mode of	Operation		
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal							
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb	Pb	Pb
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
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.) - Wound							
	Other (spec.) - Gynecological							
	Other (spec.) - Endoscopy							
	Other (spec.) -							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel							
	Other (spec.) -							

Additional Comm	iens.						
Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).						
Subscript "b":	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 imaging for guidance of trans-vaginal biopsy.						
Subscript "g":	For Adult and Pediatric patients.						
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds						

Prescription Use Only (per 21 CFR 801.109)

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Office of In Vitro Diagnostic and Radiological Health	
510(k) Number:	

^{**}Amplitude Doppler (Color Flow Angiography), 3D Imaging, Omni Directional M mode, Wide View, Contrast Imaging, Real Time Tissue Elastography

System: Noblus
Transducer: L44

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

Clinical Application	1				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	P	P		P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic							
Fetal Imaging	Adult Cephalic							
& Other	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.) - Wound							
	Other (spec.) - Gynecological							
	Other (spec.) - Endoscopy							
	Other (spec.) -							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel	P	P	P		P	P	P
Vessel	Other (spec.) -							

N = new indication. P = previously cleared in K142368

Additional Comments:

raditional Commi	VIII.O.						
Subscript "a":	"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 imaging for guidance of trans-vaginal biopsy.						
Subscript "g":	For Adult and Pediatric patients.						
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds						

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Office of In Vitro Diagnostic and Radiological Health
510(k) Number:_____

^{*}Combination of each operating mode, B, M, PWD, and Color Doppler; B/B, B/M, B/PW, B/CW, CFM-B/CW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW

^{**}Amplitude Doppler (Color Flow Angiography), 3D Imaging, Omni Directional M mode, Wide View, Contrast Imaging, Real Time Tissue Elastography

 System:
 Noblus

 Transducer:
 L441

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

Clinical Application		Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	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	P	P		P	P	P	
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd	
	Neonatal Cephalic								
Fetal Imaging	Adult Cephalic								
& Other	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.) - Wound								
	Other (spec.) - Gynecological								
	Other (spec.) - Endoscopy								
	Other (spec.) -								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Trans-esophageal (card.)								
	Other (spec.)								
Peripheral	Peripheral vessel	P	P	P		P	P	P	
Vessel	Other (spec.) -								

N = new indication. P = previously cleared in K142368

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 imaging for guidance of trans-vaginal biopsy.
Subscript "g":	For Adult and Pediatric patients.
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds

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

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Office of In Vitro Diagnostic and Radiological Health
510(k) Number:_____

^{*}Combination of each operating mode, B, M, PWD, and Color Doppler; B/B, B/M, B/PW, B/CW, CFM-B/CW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW

^{**}Amplitude Doppler (Color Flow Angiography), 3D Imaging, Omni Directional M mode, Wide View, Contrast Imaging, Real Time Tissue Elastography

System: Noblus
Transducer: L44LA
Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

inical Application			_		Mode of	Operation	0 1: 1: 1	Other**
General	Specific	В	М	PWD	CWD	Color	Combined*	
(Track I only)	(Tracks I & III)					Doppler	(Spec.)	(Spec.)
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal							
	Intra-operative (Spec.)	P	P	P		P	P	P
	Intra-operative (Neuro.)							
	Laparoscopic	P	P	P		P	P	P
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
Fetal Imaging	Adult Cephalic							
& Other	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)				_			
	Musculo-skel. (Convent.)			_				
	Musculo-skel. (Superfic.)			1				
	Intra-luminal						_	
	Other (spec.) - Wound							
	Other (spec.) - Gynecological							
	Other (spec.) - Endoscopy							
	Other (spec.) -							
	Cardiac Adult					-		
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.) -							

^{*}Combination of each operating mode, B, M, PWD, and Color Doppler; B/B, B/M, B/PW, B/CW, CFM-B/CW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-D/DW

Additional Comments

Additional Commi		
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 imaging for guidance of trans-vaginal biopsy.	
Subscript "g":	For Adult and Pediatric patients.	
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds	

Prescription Use Only (per 21 CFR 801.109)

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Office of In Vitro Diagnostic and Radiological Health	
510(k) Number:	

^{**}Amplitude Doppler (Color Flow Angiography), 3D Imaging, Omni Directional M mode, Wide View, Contrast Imaging, Real Time Tissue Elastography

System:

Noblus

Transducer:

L44LA1

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

linical Application	1		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								
	Intra-operative (Spec.)	P	P	P		P	P	P	
	Intra-operative (Neuro.)								
	Laparoscopic	P	P	P		P	P	P	
	Pediatric								
	Small Organ (Spec.)								
	Neonatal Cephalic								
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.) - Wound								
	Other (spec.) - Gynecological								
	Other (spec.) - Endoscopy								
	Other (spec.) -								
	Cardiac Adult								
Cardiac	Cardiac Pediatric								
	Trans-esophageal (card.)								
	Other (spec.)								
Peripheral	Peripheral vessel								
Vessel	Other (spec.) -								

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 imaging for guidance of trans-vaginal biopsy.
Subscript "g":	For Adult and Pediatric patients.
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds

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:	
	Division of Radiological Health Office of In Vitro Diagnostic and Radiological Health

^{*}Combination of each operating mode, B, M, PWD, and Color Doppler; B/B, B/M, B/PW, B/CW, CFM-B/CW, CFM-B/CFM-B, CFM-B/CFM-M,

^{**}Amplitude Doppler (Color Flow Angiography), 3D Imaging, Omni Directional M mode, Wide View

System:	Noblus	
Transducer:	L55	

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

Clinical Application	1	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	P	P		P	P	P	
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd	
	Neonatal Cephalic								
Fetal Imaging	Adult Cephalic								
& Other	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.) - Wound	Ph	Ph	Ph		Ph	Ph	Ph	
	Other (spec.) - Gynecological								
	Other (spec.) - Endoscopy								
	Other (spec.) -			_					
	Cardiac Adult								
Cardiac	Cardiac Pediatric								
	Trans-esophageal (card.)								
	Other (spec.)								
Peripheral	Peripheral vessel	P	P	P		P	P	P	
Vessel	Other (spec.) -								

N = new indication. P = previously cleared in K142368

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 imaging for guidance of trans-vaginal biopsy.
Subscript "g":	For Adult and Pediatric patients.
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (per 21 CFR 801.109)

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

^{*}Combination of each operating mode, B, M, PWD, and Color Doppler; B/B, B/M, B/PW, B/CW, CFM-B/CW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW

^{**}Amplitude Doppler (Color Flow Angiography), 3D Imaging, Omni Directional M mode, Wide View, Contrast Imaging, Real Time Tissue Elastography

System:

Transducer: L64

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

linical 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	P	P		P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic							
Fetal Imaging	Adult Cephalic							
& Other	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.) - Wound	Ph	Ph	Ph		Ph	Ph	Ph
	Other (spec.) - Gynecological							
	Other (spec.) - Endoscopy							
	Other (spec.) -							
•	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel	P	P	P		P	P	P
Vessel	Other (spec.) - P = previously cleared in K142368							

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 imaging for guidance of trans-vaginal biopsy.	
Subscript "g":	For Adult and Pediatric patients.	
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds	

Prescription Use Only (per 21 CFR 801.109)

(PLEASE DO NO WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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:	

^{*}Combination of each operating mode, B, M, PWD, and Color Doppler; B/B, B/M, B/PW, B/CW, CFM-B/CW, 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 Tissue Elastography

System:

R41R

Transducer:

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

nical 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							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic						_	
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
Fetal Imaging	Adult Cephalic							
& Other	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.) - Wound							
	Other (spec.) - Gynecological							
	Other (spec.) - Endoscopy							
	Other (spec.) -							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.) - P = previously cleared in K142368							

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

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

Additional	Comments
radultional	Comments

Additional Commi		
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 imaging for guidance of trans-vaginal biopsy.	
Subscript "g":	For Adult and Pediatric patients.	
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds	

Prescription Use Only (per 21 CFR 801.109)

(PLEASE DO NO 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:	

System:

Noblus S21

Transducer:

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

linical 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	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								
Fetal Imaging	Adult Cephalic	P	P	P	P	P	Р	P	
& Other	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)			_			4		
	Musculo-skel. (Superfic.)								
	Intra-luminal								
	Other (spec.) - Wound								
	Other (spec.) - Gynecological								
	Other (spec.) - Endoscopy				L				
	Other (spec.) -								
	Cardiac Adult	P	P	P	P	P	P	P	
Cardiac	Cardiac Pediatric	P	P	P	P	P	P	P	
	Trans-esophageal (card.)								
	Other (spec.)								
Peripheral	Peripheral vessel	P	P	P	P	P	P	P	
Vessel	Other (spec.) -								

N = new indication. P = previously cleared in K142368

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 imaging for guidance of trans-vaginal biopsy.	
Subscript "g":	For Adult and Pediatric patients.	
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds	

Prescription Use Only (per 21 CFR 801.109)

(PLEASE DO NO WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

^{*}Combination of each operating mode, B, M, PWD, and Color Doppler; B/B, B/M, B/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

^{**}Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging, 3D Imaging, Omni Directional M mode, Contrast Imaging

 System:
 Noblus

 Transducer:
 S211

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

linical Application	1				Mode of	Operation		
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
	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							
Fetal Imaging	Adult Cephalic	P	P	P	P	P	P	P
& Other	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) - Wound				_			
	Other (spec.) - Gynecological							
	Other (spec.) - Endoscopy							
	Other (spec.) -							
	Cardiac Adult	P	P	P	P	P	P	P
Cardiac	Cardiac Pediatric	P	P	P	P	P	P	P
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel	P	P	P	P	P	P	P
Vessel	Other (spec.) -							

N = new indication. P = previously cleared in K142368

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 imaging for guidance of trans-vaginal biopsy.	
Subscript "g":	For Adult and Pediatric patients.	
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds	

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:	

^{*}Combination of each operating mode, B, M, PWD, and Color Doppler; B/B, B/M, B/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

^{**}Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging, 3D Imaging, Omni Directional M mode, Contrast Imaging

System:

Noblus

Transducer:

S31

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

Clinical Application	Mode of Operation								
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)	
Ophthalmic	Ophthalmic								
	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	
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.) - Wound								
	Other (spec.) - Gynecological								
	Other (spec.) - Endoscopy								
	Other (spec.) -				, I				
	Cardiac Adult	P	P	P	P	P	P	P	
Cardiac	Cardiac Pediatric	P	P	P	P	P	P	P	
	Trans-esophageal (card.)								
	Other (spec.)								
Peripheral	Peripheral vessel								
Vessel	Other (spec.) -								

N = new indication. P = previously cleared in K142368

Additional Comments:

ridditional Comm.	lents.	_
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 imaging for guidance of trans-vaginal biopsy.	
Subscript "g":	For Adult and Pediatric patients.	
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds	

Prescription Use Only (per 21 CFR 801.109)

(PLEASE DO NO WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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

^{*}Combination of each operating mode, B, M, PWD, and Color Doppler; B/B, B/M, B/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

^{**}Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging, 3D Imaging, Omni Directional M mode

System:

Transducer:

S31KP

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

nical Application Mode of Operation General Specific Color Combined*								
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal							
	Intra-operative (Spec.)					_		
	Intra-operative (Neuro.)	N	N	N		N	N	N
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
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.) - Wound							
	Other (spec.) - Gynecological							
	Other (spec.) - Endoscopy							
	Other (spec.) -							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.) -							

Additional Comments:

Additional Commi	Cits.	
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 imaging for guidance of trans-vaginal biopsy.	
Subscript "g":	For Adult and Pediatric patients.	
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds	

Prescription Use Only (per 21 CFR 801.109)

(PLEASE DO NO WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

^{*}Combination of each operating mode, B, M, PWD, and Color Doppler; B/B, B/M, B/PW, B/CW, CFM-B/CW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW

^{**}Amplitude Doppler (Color Flow Angiography), Omni Directional M mode

System:

Noblus

Transducer:

S3ESS/S3ESL

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

ical Application					Mode of	Operation	0 1: 1¢ T	0.1 **
General Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
•	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
etal Imaging	Adult Cephalic							
& Other	Trans-rectal				_			
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)	Pg	Pg	Pg	Pg	Pg	Pg	Pg
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) - Wound							
	Other (spec.) - Gynecological							
	Other (spec.) - Endoscopy							
	Other (spec.) -							
	Cardiac Adult							1
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)	Pg	Pg	Pg	Pg	Pg	, Pg	Pg .
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.) -							

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

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 imaging for guidance of trans-vaginal biopsy.	
Subscript "g":	For Adult and Pediatric patients.	
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds	

Prescription Use Only (per 21 CFR 801.109)

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

^{**}Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging, 3D Imaging, Omni Directional M mode

Noblus

Transducer: S3ESEL

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

nical Application					Mode of	Operation	T	0.1 44
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal				1			
	Intra-operative (Spec.)		_					
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
Fetal Imaging	Adult Cephalic							
& Other	Trans-rectal							
	Trans-vaginal			_				
	Trans-urethral							
	Trans-esoph. (non-Card.)	Pg	Pg	Pg	Pg	Pg	Pg	Pg
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)	-7						
	Intra-luminal							
	Other (spec.) - Wound							
	Other (spec.) - Gynecological							
	Other (spec.) - Endoscopy							
	Other (spec.) -							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)	Pg	Pg	Pg	Pg	Pg	Pg	Pg
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.) -							

Additional Comments:

Subscript "b": Includes	
	imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "c": Includes	imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
	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	imaging for guidance of trans-vaginal biopsy.
Subscript "g": For Adul	It and Pediatric patients.
Subscript "h": Includes	imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (per 21 CFR 801.109)

(PLEASE DO NO 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:_

> > Page 44 of 51

^{*}Combination of each operating mode, B, M, PWD, and Color Doppler; B/B, B/M, B/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

^{**}Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging, 3D Imaging, Omni Directional M mode

System: Noblus
Transducer: S3ESL1

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

linical Application	ioone and account miniging or many				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							
	Intra-operative (Spec.)						n	
	Intra-operative (Neuro.)							
	Laparoscopic						1	
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
Fetal Imaging	Adult Cephalic							
& Other	Trans-rectal						,	
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)	Pg	Pg	Pg	Pg	Pg	Pg	Pg
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) - Wound							
	Other (spec.) - Gynecological							
	Other (spec.) - Endoscopy				2.5			
	Other (spec.) -							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)	Pg	Pg	Pg	Pg	Pg	Pg	Pg
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.) -							

N = new indication. P = previously cleared in K142368

Additional Comments:

Additional Comme	
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 imaging for guidance of trans-vaginal biopsy.
Subscript "g":	For Adult and Pediatric patients.
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (per 21 CFR 801.109)

(PLEASE DO NO WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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

^{*}Combination of each operating mode, B, M, PWD, and Color Doppler; B/B, B/M, B/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

^{**}Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging, 3D Imaging, Omni Directional M mode

System:

Noblus

Transducer:

VC34A

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

nical 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	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								
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.) - Wound								
	Other (spec.) - Gynecological								
	Other (spec.) - Endoscopy								
	Other (spec.) -			-					
	Cardiac Adult								
Cardiac	Cardiac Pediatric								
	Trans-esophageal (card.)								
	Other (spec.)								
Peripheral	Peripheral vessel								
Vessel	Other (spec.) -	1							

^{*}Combination of each operating mode, B, M, PWD, and Color Doppler; B/B, B/M, B/PW, B/CW, CFM-B/CW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW

Additional Comments:

raditional Committee		
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 imaging for guidance of trans-vaginal biopsy.	
Subscript "g":	For Adult and Pediatric patients.	
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds	

Prescription Use Only (per 21 CFR 801.109)

(PLEASE DO NO WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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

^{**}Amplitude Doppler (Color Flow Angiography), 4D Imaging, Omni Directional M mode

System:

Noblus

Transducer: UST-2265-2

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

nical 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								
	Intra-operative (Spec.)		_						
	Intra-operative (Neuro.)								
	Laparoscopic								
	Pediatric								
	Small Organ (Spec.)								
	Neonatal Cephalic								
Fetal Imaging	Adult Cephalic								
& Other	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)						L		
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic.)								
	Intra-luminal								
	Other (spec.) - Wound								
	Other (spec.) - Gynecological								
	Other (spec.) - Endoscopy								
	Other (spec.) -								
	Cardiac Adult				P				
Cardiac	Cardiac Pediatric				P				
	Trans-esophageal (card.)								
	Other (spec.)								
Peripheral	Peripheral vessel				P				
Vessel	Other (spec.) -				_				

Additional	Comments:
Additional	Committees.

Additional Comm	ients:	
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 imaging for guidance of trans-vaginal biopsy.	
Subscript "g":	For Adult and Pediatric patients.	
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds	

Prescription Use Only (per 21 CFR 801.109)

(PLEASE DO NO WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

System:

Noblus

Transducer:

EB-1970UK

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

Clinical Application		Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)	
Ophthalmic	Ophthalmic								
	Fetal			_					
	Abdominal								
	Intra-operative (Spec.)								
	Intra-operative (Neuro.)								
	Laparoscopic								
	Pediatric								
	Small Organ (Spec.)								
	Neonatal Cephalic								
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.) - Wound								
	Other (spec.) - Gynecological	1			_				
	Other (spec.) - Endoscopy	P	P	P		P	P	P	
	Other (spec.) -								
	Cardiac Adult								
Cardiac	Cardiac Pediatric								
	Trans-esophageal (card.)								
	Other (spec.)								
Peripheral	Peripheral vessel								
Vessel	Other (spec.) -								

N = new indication. P = previously cleared in K142368

^{**}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 imaging for guidance of trans-vaginal biopsy.
Subscript "g":	For Adult and Pediatric patients.
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds

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^{*}Combination of each operating mode, B, M, PWD, and Color Doppler, B/B, B/M, B/PW, B/CW, CFM-B/CW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/DW

System:

Transducer:

EG-3270UK

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

linical Application	1	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							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
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.) - Wound			_				
	Other (spec.) - Gynecological							- n
	Other (spec.) - Endoscopy	P	P	P		P	P	P
	Other (spec.) -							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.) - P = previously cleared in K142368							

Additional Comments:

Additional Comm.			
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).	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.		
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Subscript "g":	For Adult and Pediatric patients.		
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^{*}Combination of each operating mode, B, M, PWD, and Color Doppler; B/B, B/M, B/PW, B/CW, CFM-B/CW, CFM-B/CFM-B, CFM-B/CFM-M,

^{**}Amplitude Doppler (Color Flow Angiography), 3D Imaging, Wide View, Contrast Imaging, Real Time Tissue Elastography

System:

EG-3670URK Transducer:

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

Clinical Application	flow analysis if the human body as follows: Mode of Operation							
General	Specific	D.	1	PWD	CWD	Color	Combined*	Other**
(Track I only)	(Tracks I & III)	В	М	PWD	CWD	Doppler	(Spec.)	(Spec.)
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal							
	Intra-operative (Spec.)					_		
	Intra-operative (Neuro.)		*					
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
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.) - Wound	1						
	Other (spec.) - Gynecological							
	Other (spec.) - Endoscopy	P	P	P		P	P	P
	Other (spec.) -							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel		1					
Vessel	Other (spec.) -							
Combination of each	P = previously cleared in K142368 ch operating mode, B, M, PWD, an	d Color Dopp	oler; B/B, B/N	M, B/PW, B/C	W, CFM-B/C	W, CFM-B/CFM	-B, CFM-B/CFM-N	М,
FM-B/PW *Amplitude Dopple	er (Color Flow Angiography), 3D I	maging, Cont	rast Imaging,	Real Time Ti	ssue Elastogra	phy		
Additional Commen								
ubscript "a":	Includes imaging for guidance of	percutaneous	biopsy of ab	dominal organ		es (including amr		

Additional Collin		
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.	
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Subscript "e":	Includes imaging for guidance of trans-rectal biopsy.	
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Subscript "g":	For Adult and Pediatric patients.	
Subscript "h":	Includes imaging for Cavernous/Non-Cavernous wounds	

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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:	
	Division of Radiological Health Office of In Vitro Diagnostic and Radiological Health

System:

Noblus

Transducer:

EG-3870UTK

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

linical Application			Mode of Operation							
General	Specific	В	М	PWD	CWD	Color	Combined*	Other**		
(Track I only)	(Tracks I & III)	ь	141	1,112	0112	Doppler	(Spec.)	(Spec.)		
Ophthalmic	Ophthalmic									
	Fetal									
	Abdominal									
	Intra-operative (Spec.)									
	Intra-operative (Neuro.)			_						
	Laparoscopic									
	Pediatric									
	Small Organ (Spec.)									
	Neonatal Cephalic									
Fetal Imaging	Adult Cephalic									
& Other	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skel. (Convent.)				2					
	Musculo-skel. (Superfic.)									
	Intra-luminal									
	Other (spec.) - Wound									
	Other (spec.) - Gynecological									
	Other (spec.) - Endoscopy	P	P	P	×	P	P	P		
	Other (spec.) -									
	Cardiac Adult									
Cardiac	Cardiac Pediatric									
	Trans-esophageal (card.)									
	Other (spec.)									
Peripheral	Peripheral vessel									
Vessel	Other (spec.) -									
	P = previously cleared in K142368									
	ch operating mode, B, M, PWD, and	d Color Dopp	oler; B/B, B/N	M, B/PW, B/C	W, CFM-B/C	W, CFM-B/CFM	-B, CFM-B/CFM-N	Л,		
M-B/PW										
mplitude Doppl	er (Color Flow Angiography), 3D In	naging, Wide	View, Cont	rast Imaging, I	Real Time Tiss	sue Elastography				

Additional	Comments
Additional	Comments

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).	
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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

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. 10 Fairfield Boulevard
Wallingford, CT 06492-5903
On behalf of
HITACHI, LTD
2-16-1, Higashi-Ueno, Taito-ku
Tokyo, 110-0015, JAPAN

Primary Contact Person: Angela Van Arsdale R.A. / Q.A. Manager

Telephone: (203) 269-5088 Ext: 346

Fax Number: (203) 269-6075

Date Prepared: October 17, 2016

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

Device Proprietary Name – NOBLUS™ Ultrasound Diagnostic System Common name - Ultrasound Diagnostic 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):

NoblusTM Ultrasound Diagnostic System (K142368)

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
- o 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:

The Hitachi Noblus™ Ultrasound Diagnostic System is intended for use by trained personnel (doctor, sonographer, etc.) for the diagnostic ultrasound evaluation of Abdominal, Cardiac, Intra-operative (Spec.), Intra-operative (Neuro), Trans-esophageal (Cardiac/Non-Cardiac) – Adult/Pediatric, Wound (Cavernous/Non-Cavernous), 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 Hitachi Noblus™ Ultrasound Diagnostic System are B mode, M mode, PW mode (Pulse Wave Doppler), CW mode (Continuous Wave Doppler), Color Doppler, Amplitude Doppler (Color Flow Angiography), TDI (Tissue Doppler Imaging), 3D Imaging, 4D Imaging, and Real Time Tissue Elastography

6. Comparison to predicate device:

The Hitachi NOBLUS™ Ultrasound Diagnostic System is equivalent to the predicate devices the Hitachi Noblus (K142368). The NOBLUS™ has been modified to include an additional indication, additional probes / accessories and new materials of manufacture that fall within predicate material specifications. The subject and predicate devices are Track III systems.

	Predicate Device	Subject Device
	Noblus	Noblus
	(K142368)	
Intended Use:	The Hitachi Noblus™ Ultrasound Diagnostic	The Hitachi Noblus™ Ultrasound Diagnostic
	System is intended for use by trained personnel	System is intended for use by trained personnel
	(doctor, sonographer, etc.) for the diagnostic	(doctor, sonographer, etc.) for the diagnostic
	ultrasound evaluation of Abdominal, Cardiac,	ultrasound evaluation of Abdominal, Cardiac,
	Intra-operative (Spec.), Trans-esophageal	Intra-operative (Spec.), Intra-operative (Neuro),
	(Cardiac/Non-Cardiac) – Adult/Pediatric, Wound	Trans-esophageal (Cardiac/Non-Cardiac) –
	(Cavernous/Non-Cavernous), Fetal, Pediatric,	Adult/Pediatric, Wound (Cavernous/Non-
	Small Organ, Peripheral vessel, Biopsy, Trans-	Cavernous), Fetal, Pediatric, Small Organ,
	rectal, Trans-vaginal, Musculoskeletal (Convent.	Peripheral vessel, Biopsy, Trans-rectal, Trans-
	/ Superfic.), Neonatal Cephalic, Adult Cephalic,	vaginal, Musculoskeletal (Convent. / Superfic.),
	Endoscopy, Intra-luminal, Gynecology, Urology,	Neonatal Cephalic, Adult Cephalic, Endoscopy,
	and Laparoscopic clinical applications.	Intra-luminal, Gynecology, Urology, and
		Laparoscopic clinical applications.
	The Modes of Operation of the Noblus TM	
	Ultrasound Diagnostic System are B mode, M	The Modes of Operation of the Noblus TM
	mode, PW mode (Pulse Wave Doppler), CW	Ultrasound Diagnostic System are B mode, M
	mode (Continuous Wave Doppler), Color	mode, PW mode (Pulse Wave Doppler), CW
	Doppler, Amplitude Doppler (Color Flow	mode (Continuous Wave Doppler), Color
	Angiography), TDI (Tissue Doppler Imaging),	Doppler, Amplitude Doppler (Color Flow
	3D Imaging, 4D Imaging, and Real Time Tissue	Angiography), TDI (Tissue Doppler Imaging),
	Elastography.	3D Imaging, 4D Imaging, and Real Time Tissue
		Elastography.
FDA Track:	1 probe / 3 probes (with Probe extension unit)	1 probe / 3 probes (with Probe extension unit)
Probes:	Convex, Linear, Sector, 4D, Other, EUS	Convex, Linear, Sector, 4D, Other, EUS
Transmit Channel:	64	64
Display Modes:	Combinations of	Combinations of
	B, B/B, B/M, M, B/PW, PW, CW, B/CW, CFM-	B, B/B, B/M, M, B/PW, PW, CW, B/CW, CFM-
	B/CW, CFM-B, CFM-B/CFM-B, CFM-B/CFM-	B/CW, CFM-B, CFM-B/CFM-B, CFM-B/CFM-
	M, CFM-M, CFM-B/PW, TDI-B,TDI-B/B,TDI-	M, CFM-M, CFM-B/PW, TDI-B,TDI-B/B,TDI-
	B/M, TDI-M,TDI-B/PW,TDI-PW	B/M, TDI-M,TDI-B/PW,TDI-PW

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 NoblusTM Ultrasound Diagnostic scanner is substantially equivalent in safety and effectiveness to the predicate device:

- The subject and predicate device(s) are both indicated for ultrasound Diagnostic 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