



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

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

December 6, 2016

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 Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

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

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

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

Sincerely yours,

A handwritten signature in black ink, appearing to read "R. Ochs", is written over a faint, large "FDA" watermark.

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

Enclosure

## Indications for Use

510(k) Number (if known)  
K160559

Device Name  
NOBLUS™ Ultrasound Diagnostic System

### Indications for Use (Describe)

The 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.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D)

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

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: Noblus  
 Transducer: All connectable probes

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

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

N = new indication. P = previously cleared in 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, 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

**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: \_\_\_\_\_



# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus

Transducer: C221

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

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

N = new indication. P = previously cleared in 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, CFM-B/PW

\*\*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 Cavemous/Non-Cavemous wounds

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**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: Noblus

Transducer: C22K

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

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

N = new indication. P = previously cleared in 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, CFM-B/PW

\*\*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

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**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: Noblus  
Transducer: C22P

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

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

N = new indication. P = previously cleared in 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, CFM-B/PW

\*\*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 Cavertous/Non-Cavertous wounds

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



**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: Noblus  
 Transducer: C22T

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

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

N = new indication. P = previously cleared in 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, CFM-B/PW,

\*\*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

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



**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: Noblus  
Transducer: C25

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

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

N = new indication. P = previously cleared in 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, CFM-B/PW  
\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Omni Directional M mode, Wide View, Contrast Imaging, Real Time Tissue Elastography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).  
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).  
Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.  
Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.  
Subscript "e": Includes imaging for guidance of trans-rectal biopsy.  
Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.  
Subscript "g": For Adult and Pediatric patients.  
Subscript "h": Includes imaging for Cavertous/Non-Cavertous 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 Sign – Off)  
Division of Radiological Health  
Office of In Vitro Diagnostic and Radiological Health  
510(k) Number: \_\_\_\_\_

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus  
Transducer: C251

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

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

N = new indication. P = previously cleared in 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, CFM-B/PW

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

## Additional Comments:

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of trans-rectal biopsy.
Subscript "f":	Includes imaging for guidance of trans-vaginal biopsy.
Subscript "g":	For Adult and Pediatric patients.
Subscript "h":	Includes imaging for Cavemous/Non-Cavemous 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: \_\_\_\_\_

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: Noblus  
 Transducer: C35

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

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

N = new indication. P = previously cleared in 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, CFM-B/PW, CFM-B/PW

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

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



**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: Noblus  
 Transducer: C41

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

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

N = new indication. P = previously cleared in 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, CFM-B/PW

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

**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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# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus

Transducer: C41B

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

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

N = new indication. P = previously cleared in 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, CFM-B/PW

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

Additional Comments:

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

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

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

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

Subscript "e": Includes imaging for guidance of trans-rectal biopsy.

Subscript "f": Includes 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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# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus

Transducer: C41L47RP

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

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

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, CFM-B/PW

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Wide View, 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 Cavemous/Non-Cavemous wounds

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**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: Noblus  
 Transducer: C41V

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

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

N = new indication. P = previously cleared in 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, CFM-B/PW

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

**Additional Comments:**

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

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

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

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

Subscript "e": Includes imaging for guidance of trans-rectal biopsy.

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

Subscript "g": For Adult and Pediatric patients.

Subscript "h": Includes imaging for Cavemous/Non-Cavemous wounds

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**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: Noblus  
 Transducer: C41V1

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

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

N = new indication. P = previously cleared in 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, CFM-B/PW

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

**Additional Comments:**

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of trans-rectal biopsy.
Subscript "f":	Includes imaging for guidance of trans-vaginal biopsy.
Subscript "g":	For Adult and Pediatric patients.
Subscript "h":	Includes imaging for Cavertous/Non-Cavertous wounds

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# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus

Transducer: C42

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

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

N = new indication. P = previously cleared in 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, CFM-B/PW

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Wide View, 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 Cavemous/Non-Cavemous wounds

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# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus  
Transducer: C42K

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

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

N = new indication. P = previously cleared in 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, CFM-B/PW

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

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

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus

Transducer: C42T

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

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

N = new indication. P = previously cleared in 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, CFM-B/PW

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

## Additional Comments:

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of trans-rectal biopsy.
Subscript "f":	Includes imaging for guidance of trans-vaginal biopsy.
Subscript "g":	For Adult and Pediatric patients.
Subscript "h":	Includes imaging for Cavertous/Non-Cavertous wounds

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**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: Noblus  
 Transducer: CC41R

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

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

N = new indication. P = previously cleared in 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, CFM-B/PW

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

**Additional Comments:**

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of trans-rectal biopsy.
Subscript "f":	Includes imaging for guidance of trans-vaginal biopsy.
Subscript "g":	For Adult and Pediatric patients.
Subscript "h":	Includes imaging for Cavemous/Non-Cavemous wounds

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



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus  
 Transducer: EUP-B512

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

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

N = new indication. P = previously cleared in 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, CFM-B/PW, CFM-B/PW

\*\*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 Cavemous/Non-Cavemous wounds

Prescription Use Only (per 21 CFR 801.109)

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# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

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)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) - Wound							
	Other (spec.) - Gynecological							
	Other (spec.) - Endoscopy							
	Other (spec.) -							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.) -							

N = new indication. P = previously cleared in 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, CFM-B/PW  
 \*\*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

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**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: Noblus  
 Transducer: EUP-C715

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

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

N = new indication. P = previously cleared in 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, CFM-B/PW  
 \*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Omni Directional M mode, Wide View, Contrast Imaging, Real Time Tissue Elastography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).  
 Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).  
 Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.  
 Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.  
 Subscript "e": Includes imaging for guidance of trans-rectal biopsy.  
 Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.  
 Subscript "g": For Adult and Pediatric patients.  
 Subscript "h": Includes imaging for Cavemous/Non-Cavemous wounds

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# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus

Transducer: EUP-CC531S

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

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

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, CFM-B/PW  
 \*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Contrast Imaging, Real Time Tissue Elastography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).  
 Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).  
 Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.  
 Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.  
 Subscript "e": Includes imaging for guidance of trans-rectal biopsy.  
 Subscript "f": Includes 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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**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: Noblus

Transducer: EUP-L53L

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

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

N = new indication. P = previously cleared in 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, CFM-B/PW

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Wide View, 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 Cavertous/Non-Cavertous wounds

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# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus

Transducer: EUP-L74M

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

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

N = new indication. P = previously cleared in 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, CFM-B/PW

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

## Additional Comments:

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

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

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

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

Subscript "e": Includes imaging for guidance of trans-rectal biopsy.

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

Subscript "g": For Adult and Pediatric patients.

Subscript "h": Includes imaging for Cavemous/Non-Cavemous wounds

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus  
 Transducer: EUP-O53T

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

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

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, CFM-B/PW  
 \*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Wide View, Contrast Imaging, Real Time Tissue Elastography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).  
 Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).  
 Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.  
 Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.  
 Subscript "e": Includes imaging for guidance of trans-rectal biopsy.  
 Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.  
 Subscript "g": For Adult and Pediatric patients.  
 Subscript "h": Includes imaging for Cavemous/Non-Cavemous wounds

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# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

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)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb	Pb	Pb
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	P	P
	Musculo-skel. (Superfic.)	P	P	P		P	P	P
	Intra-luminal							
	Other (spec.) - Wound							
	Other (spec.) - Gynecological							
	Other (spec.) - Endoscopy							
	Other (spec.) -							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P
	Other (spec.) -							

N = new indication. P = previously cleared in 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, CFM-B/PW

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Omni Directional M mode, Wide View, 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 Cavemous/Non-Cavemous wounds

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# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus  
Transducer: EUP-O732T

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

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

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, CFM-B/PW  
 \*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Wide View, Contrast Imaging, Real Time Tissue Elastography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).  
 Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).  
 Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.  
 Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.  
 Subscript "e": Includes imaging for guidance of trans-rectal biopsy.  
 Subscript "f": Includes 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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# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus

Transducer: EUP-OL334

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

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

N = new indication. P = previously cleared in 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, CFM-B/PW

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

## Additional Comments:

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of trans-rectal biopsy.
Subscript "f":	Includes imaging for guidance of trans-vaginal biopsy.
Subscript "g":	For Adult and Pediatric patients.
Subscript "h":	Includes imaging for Cavemous/Non-Cavemous wounds

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# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus

Transducer: EUP-R54AW-19, -33

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

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

N = new indication. P = previously cleared in 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, CFM-B/PW

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

## Additional Comments:

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of trans-rectal biopsy.
Subscript "f":	Includes 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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**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

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)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	P	P
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) - Wound							
	Other (spec.) - Gynecological							
	Other (spec.) - Endoscopy							
	Other (spec.) -							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P
	Other (spec.) -							

N = new indication. P = previously cleared in 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, CFM-B/PW

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

**Additional Comments:**

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of trans-rectal biopsy.
Subscript "f":	Includes 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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 510(k) Number: \_\_\_\_\_

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus  
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)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb	Pb	Pb
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) - Wound							
	Other (spec.) - Gynecological							
	Other (spec.) - Endoscopy							
	Other (spec.) -							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.) -							

N = new indication. P = previously cleared in 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, CFM-B/PW, CFM-B/PW

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

## Additional Comments:

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

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

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

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

Subscript "e": Includes imaging for guidance of trans-rectal biopsy.

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

Subscript "g": For Adult and Pediatric patients.

Subscript "h": Includes imaging for Cavemous/Non-Cavemous wounds

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

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: Nobius  
Transducer: L44

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

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

N = new indication. P = previously cleared in 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, CFM-B/PW

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

**Additional Comments:**

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).  
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).  
Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.  
Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.  
Subscript "e": Includes imaging for guidance of trans-rectal biopsy.  
Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.  
Subscript "g": For Adult and Pediatric patients.  
Subscript "h": Includes imaging for Cavemous/Non-Cavemous wounds

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# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

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)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	P	P
	Musculo-skel. (Superfic.)	P	P	P		P	P	P
	Intra-luminal							
	Other (spec.) - Wound							
	Other (spec.) - Gynecological							
	Other (spec.) - Endoscopy							
	Other (spec.) -							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P
	Other (spec.) -							

N = new indication. P = previously cleared in 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, CFM-B/PW

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

Additional Comments:

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

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

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

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

Subscript "e": Includes imaging for guidance of trans-rectal biopsy.

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

Subscript "g": For Adult and Pediatric patients.

Subscript "h": Includes imaging for Cavemous/Non-Cavemous wounds

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**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: Noblus  
 Transducer: L44LA

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

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

N = new indication. P = previously cleared in 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, CFM-B/PW

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

**Additional Comments:**

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

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

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

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

Subscript "e": Includes imaging for guidance of trans-rectal biopsy.

Subscript "f": Includes 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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**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: Noblus  
 Transducer: L44LA1

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

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
	Fetal							
Fetal Imaging & Other	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							
	Adult Cephalic							
	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	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.) -							

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, CFM-B/PW

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

**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 Cavemous/Non-Cavemous wounds

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**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: Noblus  
 Transducer: L55

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

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

N = new indication. P = previously cleared in 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, CFM-B/PW

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

**Additional Comments:**

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).  
 Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).  
 Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.  
 Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.  
 Subscript "e": Includes imaging for guidance of trans-rectal biopsy.  
 Subscript "f": Includes 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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# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus  
Transducer: L64

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

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

N = new indication. P = previously cleared in 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, CFM-B/PW

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Omni Directional M mode, Wide View, 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 Cavertous/Non-Cavertous wounds

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

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: Noblus  
 Transducer: R41R

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

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

N = new indication. P = previously cleared in 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, CFM-B/PW

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

**Additional Comments:**

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

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

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

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

Subscript "e": Includes imaging for guidance of trans-rectal biopsy.

Subscript "f": Includes 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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**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: Noblus  
 Transducer: S21

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

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

N = new indication. P = previously cleared in 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, 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

**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 Cavemous/Non-Cavemous wounds

*Prescription Use Only (per 21 CFR 801.109)*

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**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: Noblus

Transducer: S211

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

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

N = new indication. P = previously cleared in 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, 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

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

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

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)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P	P	P	P	P
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P
	Small Organ (Spec.)							
	Neonatal Cephalic	P	P	P	P	P	P	P
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) - Wound							
	Other (spec.) - Gynecological							
	Other (spec.) - Endoscopy							
	Other (spec.) -							
Cardiac	Cardiac Adult	P	P	P	P	P	P	P
	Cardiac Pediatric	P	P	P	P	P	P	P
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.) -							

N = new indication. P = previously cleared in 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, 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

**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 Cavemous/Non-Cavemous wounds

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# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus

Transducer: S31KP

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

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

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, CFM-B/PW  
 \*\*Amplitude Doppler (Color Flow Angiography), Omni Directional M mode

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).  
 Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).  
 Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.  
 Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.  
 Subscript "e": Includes imaging for guidance of trans-rectal biopsy.  
 Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.  
 Subscript "g": For Adult and Pediatric patients.  
 Subscript "h": Includes imaging for Cavemous/Non-Cavemous wounds

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

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus  
 Transducer: S3ESS/S3ESL

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

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

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, CFM-B/PW, 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

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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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus  
 Transducer: S3ESEL

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

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

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, 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

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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**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**

System: Noblus  
 Transducer: S3ESL1

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

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

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, 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

**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 Cavemous/Non-Cavemous wounds

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus  
Transducer: VC34A

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

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

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, CFM-B/PW  
\*\*Amplitude Doppler (Color Flow Angiography), 4D Imaging, Omni Directional M mode

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).  
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).  
Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.  
Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.  
Subscript "e": Includes imaging for guidance of trans-rectal biopsy.  
Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.  
Subscript "g": For Adult and Pediatric patients.  
Subscript "h": Includes imaging for Cavemous/Non-Cavemous 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: \_\_\_\_\_

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus  
 Transducer: UST-2265-2

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

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

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



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

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)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) - Wound							
	Other (spec.) - Gynecological							
Other (spec.) - Endoscopy	P	P	P		P	P	P	
Other (spec.) -								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.) -							

N = new indication. P = previously cleared in 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, CFM-B/PW  
 \*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Tissue Elastography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).  
 Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).  
 Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.  
 Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.  
 Subscript "e": Includes imaging for guidance of trans-rectal biopsy.  
 Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.  
 Subscript "g": For Adult and Pediatric patients.  
 Subscript "h": Includes imaging for Cavemous/Non-Cavemous wounds

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus  
 Transducer: EG-3270UK

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

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

N = new indication. P = previously cleared in 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, CFM-B/PW  
 \*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Wide View, Contrast Imaging, Real Time Tissue Elastography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).  
 Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).  
 Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.  
 Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.  
 Subscript "e": Includes imaging for guidance of trans-rectal biopsy.  
 Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.  
 Subscript "g": For Adult and Pediatric patients.  
 Subscript "h": Includes imaging for Cavemous/Non-Cavemous wounds

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus  
 Transducer: EG-3670URK

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

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

N = new indication. P = previously cleared in 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, CFM-B/PW  
 \*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Contrast Imaging, Real Time Tissue Elastography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).  
 Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).  
 Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.  
 Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.  
 Subscript "e": Includes imaging for guidance of trans-rectal biopsy.  
 Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.  
 Subscript "g": For Adult and Pediatric patients.  
 Subscript "h": Includes imaging for Cavemous/Non-Cavemous wounds

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# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus

Transducer: EG-3870UTK

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

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

N = new indication. P = previously cleared in 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, CFM-B/PW

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

## Additional Comments:

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

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

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

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

21 CFR 807.92, Subsection a

1. Submitter's Information

Hitachi Aloka Medical America, Inc.  
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):

Noblus™ 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
- 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.

	<b><u>Predicate Device</u></b> <b>Noblus</b> <b>(K142368)</b>	<b><u>Subject Device</u></b> <b>Noblus</b>
Intended Use:	<p>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.), 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.</p> <p>The Modes of Operation of the 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.</p>	<p>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.), <b>Intra-operative (Neuro)</b>, 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.</p> <p>The Modes of Operation of the 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.</p>
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:	<p>Combinations of</p> <p>B, B/B, B/M, M, B/PW, PW, CW, B/CW, CFM-B/CW, CFM-B, CFM-B/CFM-B, CFM-B/CFM-M, CFM-M, CFM-B/PW, TDI-B, TDI-B/B, TDI-B/M, TDI-M, TDI-B/PW, TDI-PW</p>	<p>Combinations of</p> <p>B, B/B, B/M, M, B/PW, PW, CW, B/CW, CFM-B/CW, CFM-B, CFM-B/CFM-B, CFM-B/CFM-M, CFM-M, CFM-B/PW, TDI-B, TDI-B/B, TDI-B/M, TDI-M, TDI-B/PW, TDI-PW</p>



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 Noblus™ 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**