



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

Hitachi Aloka Medical, Ltd.
% Ms. Angela Van Arsdale
Regulatory Affairs /Quality Assurance Manager
10 Fairfield Blvd.
WALLINGFORD CT 06492

January 14, 2015

Re: K142368
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: December 29, 2014
Received: December 30, 2014

Dear Ms. Van Arsdale:

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

This determination of substantial equivalence applies to the following transducers intended for use with the Noblus™ Ultrasound Diagnostic System, as described in your premarket notification:

Transducer Model Number

| | | | | |
|-----------|------------|------------|---------------|-----------|
| C22K | C22P | C25 | C251 | C35 |
| C41 | C41B | C41L47RP | C41V | C41V1 |
| C42 | C42K | CC41R | EUP-B512 | EUP-B715 |
| EUP-C715 | EUP-CC531S | EUP-L53L | EUP-L74M | EUP-O53T |
| EUP-O54J | EUP-O732T | EUP-OL334 | L34 | L44 |
| L441 | L55 | L64 | R41R | S21 |
| S211 | S31 | VC34A | UST-2265-2 | EB-1970UK |
| EG-3270UK | EG-3670URK | EG-3870UTK | S3ESS / S3ESL | |

EUP-R54AW-19 / EUP-R54AW-33

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

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

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (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 that reads "Robert A. Ochs". The signature is written in a cursive style. Behind the signature, there is a faint, semi-transparent watermark of the FDA logo.

Robert Ochs, Ph.D.
Acting 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)
K142368

Device Name
Noblus™ Ultrasound Diagnostic System

Indications for Use (Describe)

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, Biospy, Trans-rectal, Trans-vaginal, Musculoskeletal (Convent. / Superfic.), Neonatal Cephalic, Adult Cephalic, Endoscopy, Intraluminal, 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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

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

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

N = new indication. P = previously cleared in K130308

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

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

Additional Comments:

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

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

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

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

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

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

Subscript "g": For Adult and Pediatric patients.

Subscript "h": Includes imaging for Cavernous/Non-Cavernous wounds.

Prescription Use Only (per 21 CFR 801.109)

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

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

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 | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (card.) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |
| N = new indication. P = previously cleared in K130308 *Combination of each operating mode, B, M, PWD and Color Doppler. **Amplitude Doppler (Color Flow Angiography), 3D Imaging Additional Comments: | | | | | | | | |
| Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis). | | | | | | | | |
| Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures). | | | | | | | | |
| Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis. | | | | | | | | |
| Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy. | | | | | | | | |
| Subscript "e": Includes imaging for guidance of trans-rectal biopsy. | | | | | | | | |
| Subscript "f": Includes imaging for guidance of trans-vaginal biopsy. | | | | | | | | |
| Subscript "g": For Adult and Pediatric patients. | | | | | | | | |
| Subscript "h": Includes imaging for Cavernous/Non-Cavernous wounds. | | | | | | | | |

Prescription Use Only (per 21 CFR 801.109)

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

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

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 | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (card.) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |

N = new indication. P = previously cleared in K134016 & K140443

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

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

Additional Comments:

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

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

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

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

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

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

Subscript "g": For Adult and Pediatric patients.

Subscript "h": Includes imaging for Cavernous/Non-Cavernous wounds.

Prescription Use Only (per 21 CFR 801.109)

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

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

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 | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (card.) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |
| N = new indication. P = previously cleared in K130308 *Combination of each operating mode, B, M, PWD and Color Doppler. **Amplitude Doppler (Color Flow Angiography), 3D Imaging Additional Comments: | | | | | | | | |
| Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis). | | | | | | | | |
| Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures). | | | | | | | | |
| Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis. | | | | | | | | |
| Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy. | | | | | | | | |
| Subscript "e": Includes imaging for guidance of trans-rectal biopsy. | | | | | | | | |
| Subscript "f": Includes imaging for guidance of trans-vaginal biopsy. | | | | | | | | |
| Subscript "g": For Adult and Pediatric patients. | | | | | | | | |
| Subscript "h": Includes imaging for Cavernous/Non-Cavernous wounds. | | | | | | | | |

Prescription Use Only (per 21 CFR 801.109)

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

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

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 | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (card.) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |

N = new indication. P = previously cleared in K134016 & K140443

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

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

Additional Comments:

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

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

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

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

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

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

Subscript "g": For Adult and Pediatric patients.

Subscript "h": Includes imaging for Cavernous/Non-Cavernous wounds.

Prescription Use Only (per 21 CFR 801.109)

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

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

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 | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (card.) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |

N = new indication. P = previously cleared in K134016
 *Combination of each operating mode, B, M, PWD and Color Doppler.
 **Amplitude Doppler (Color Flow Angiography), 3D Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
 Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
 Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
 Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
 Subscript "e": Includes imaging for guidance of 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: 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 | 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 | | | | | | | | |
| 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 K130308 & K134016

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

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

Additional Comments:

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

Prescription Use Only (per 21 CFR 801.109)

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

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

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 | N | N | N | | N | N | N |
| | Abdominal | | | | | | | |
| | Intra-operative (Spec.) | | | | | | | |
| | Intra-operative (Neuro.) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | | | | | | | |
| | Small Organ (Spec.) | | | | | | | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | Ne | Ne | Ne | | Ne | Ne | Ne |
| | Trans-vaginal | Nf | Nf | Nf | | Nf | Nf | Nf |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Card.) | | | | | | | |
| | Musculo-skel. (Convent.) | | | | | | | |
| | Musculo-skel. (Superfic.) | | | | | | | |
| Intra-luminal | | | | | | | | |
| Other (spec.) - Wound | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (card.) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |

N = new see Appendix 1. P = previously cleared in K130308

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

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

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 | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (card.) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |

N = new indication. P = previously cleared in K134016 & K140443

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

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

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

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.) - Gynecological | P | P | P | | P | P | P | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (card.) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |

N = new indication. P = previously cleared in K130308

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

**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: 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.) - Gynecological | P | P | P | | P | P | P | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (card.) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |
| <p>N = new indication. P = previously cleared in K134016 & K140443</p> <p>*Combination of each operating mode, B, M, PWD and Color Doppler.</p> <p>**Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Tissue Elastography</p> <p>Additional Comments:</p> <p>Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).</p> <p>Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).</p> <p>Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.</p> <p>Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.</p> <p>Subscript "e": Includes imaging for guidance of trans-rectal biopsy.</p> <p>Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.</p> <p>Subscript "g": For Adult and Pediatric patients.</p> <p>Subscript "h": Includes imaging for Cavernous/Non-Cavernous wounds.</p> | | | | | | | | |

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

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 | | | | | | | | |
| 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 K130308

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

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

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 | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (card.) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |
| <p>N = new indication. P = previously cleared in K130308 & K134016</p> <p>*Combination of each operating mode, B, M, PWD and Color Doppler.</p> <p>**Amplitude Doppler (Color Flow Angiography), 3D Imaging</p> <p>Additional Comments:</p> <p>Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).</p> <p>Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).</p> <p>Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.</p> <p>Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.</p> <p>Subscript "e": Includes imaging for guidance of trans-rectal biopsy.</p> <p>Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.</p> <p>Subscript "g": For Adult and Pediatric patients.</p> <p>Subscript "h": Includes imaging for Cavernous/Non-Cavernous wounds.</p> | | | | | | | | |

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

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 | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (card.) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |

N = new indication. P = previously cleared in K134016 & K140443
 *Combination of each operating mode, B, M, PWD and Color Doppler.
 **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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 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 | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (card.) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |

N = new indication. P = previously cleared in K093466, K102901 & K110673

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

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

Additional Comments:

| | |
|----------------|--|
| Subscript "a": | Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis). |
| Subscript "b": | Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures). |
| Subscript "c": | Includes thyroid, parathyroid, breast, scrotum, penis. |
| Subscript "d": | Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy. |
| Subscript "e": | Includes imaging for guidance of 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-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 | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (card.) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |

N = new indication. P = previously cleared in K110673

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

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

Additional Comments:

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

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

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

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

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

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

Subscript "g": For Adult and Pediatric patients.

Subscript "h": Includes imaging for Cavernous/Non-Cavernous wounds.

Prescription Use Only (per 21 CFR 801.109)

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

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

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 | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (card.) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |

N = new indication. P = previously cleared in K093466, K102901 & K110673
 *Combination of each operating mode, B, M, PWD and Color Doppler.
 **Amplitude Doppler (Color Flow Angiography), 3D Imaging

Additional Comments:

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

Prescription Use Only (per 21 CFR 801.109)

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

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

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 | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (card.) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |

N = new indication. P = previously cleared in K130308

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

**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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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: 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 | | | | | | | | |
| 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 K093466, K102901 & K110673
 *Combination of each operating mode, B, M, PWD, and Color Doppler.
 **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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Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

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

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 | | | | | | | | |
| 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 K093466, K102901 & K110673
 *Combination of each operating mode, B, M, PWD, and Color Doppler.
 **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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Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

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

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 | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (card.) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |

N = new indication. P = previously cleared in K032503, K063518, K102901 & K110673

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

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

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

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 | | | | | | | | | |
| 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 K130308

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

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

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

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 | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (card.) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |

N = new indication. P = previously cleared in K110673

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

**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)

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

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

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

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 | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (card.) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |

N = new indication. P = previously cleared in K130308

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

**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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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: EUP-R54AW-19 / EUP-R54AW-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 | 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 | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (card.) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |

N = new indication. P = previously cleared in K130308

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

**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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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: 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 | | | | | | | | |
| 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 K130308 & K134016

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

**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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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: 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 | | | | | | | | |
| 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 K130308

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

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

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

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 | | | | | | | | |
| 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 K134016 & K140443

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

**Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging, 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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 Office of In Vitro Diagnostic and Radiological Health
 510(k) Number: _____

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 | Nh | Nh | Nh | | Nh | Nh | Nh | |
| 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 K130308

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

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

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

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 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 | Nh | Nh | Nh | | Nh | Nh | Nh | |
| 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 K130308

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

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

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 Office of In Vitro Diagnostic and Radiological Health
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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 | 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 | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (card.) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |

N = new indication. P = previously cleared in K134016 & K140443

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

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

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

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 | | | | | | | | |
| 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 K130308

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

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

Additional Comments:

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

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

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

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

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

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

Subscript "g": For Adult and Pediatric patients.

Subscript "h": Includes imaging for Cavernous / Non-Cavernous wounds.

Prescription Use Only (per 21 CFR 801.109)

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

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

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 | | | | | | | | |
| 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 K140443

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

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

Additional Comments:

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

Prescription Use Only (per 21 CFR 801.109)

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

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

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 | | | | | | | | |
| 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 K130308

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

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

Additional Comments:

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

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

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 Division of Radiological Health
 Office of In Vitro Diagnostic and Radiological Health
 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.) | | Ng | Ng | Ng | Ng | Ng | Ng | Ng |
| | Musculo-skel. (Convent.) | | | | | | | | |
| | Musculo-skel. (Superfic.) | | | | | | | | |
| Intra-luminal | | | | | | | | | |
| Other (spec.) - Wound | | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | | |
| | Cardiac Pediatric | | | | | | | | |
| | Trans-esophageal (card.) | | Ng | Ng | Ng | Ng | Ng | Ng | |
| | Other (spec.) | | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | | |
| | Other (spec.) | | | | | | | | |

N = new indication. P = previously cleared

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

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

Additional Comments:

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

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

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

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 | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (card.) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |

N = new indication. P = previously cleared in K130308

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

**Amplitude Doppler (Color Flow Angiography), 3D Imaging, 4D Imaging

Additional Comments:

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

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

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 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 | | | | | | | | |
| 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 K033311, K032875, K040719, K122537, K134016, K140443 & K140639 | | | | | | | | |
| 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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 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 | | | | | | | |
| Endoscopy | | P | P | P | | P | P | P |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (card.) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |
| N = new indication. P = previously cleared in K131946 & K130308 | | | | | | | | |
| Additional Comments: | | | | | | | | |
| Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis). | | | | | | | | |
| Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures). | | | | | | | | |
| Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis. | | | | | | | | |
| Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy. | | | | | | | | |
| Subscript "e": Includes imaging for guidance of trans-rectal biopsy. | | | | | | | | |
| Subscript "f": Includes imaging for guidance of trans-vaginal biopsy. | | | | | | | | |
| Subscript "g": For Adult and Pediatric patients. | | | | | | | | |
| Subscript "h": Includes imaging for Cavernous / Non-Cavernous wounds. | | | | | | | | |

Prescription Use Only (per 21 CFR 801.109)

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

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

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 | | | | | | | | |
| Endoscopy | | P | P | P | | P | P | P |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (card.) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |
| N = new indication. P = previously cleared in K130247 & K130308 | | | | | | | | |
| Additional Comments: | | | | | | | | |
| Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis). | | | | | | | | |
| Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures). | | | | | | | | |
| Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis. | | | | | | | | |
| Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy. | | | | | | | | |
| Subscript "e": Includes imaging for guidance of trans-rectal biopsy. | | | | | | | | |
| Subscript "f": Includes imaging for guidance of trans-vaginal biopsy. | | | | | | | | |
| Subscript "g": For Adult and Pediatric patients. | | | | | | | | |
| Subscript "h": Includes imaging for Cavernous / Non-Cavernous wounds. | | | | | | | | |

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

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

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 | | | | | | | | |
| Endoscopy | | P | P | P | | P | P | P |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (card.) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |
| N = new indication. P = previously cleared in K130206 & K130308 | | | | | | | | |
| Additional Comments: | | | | | | | | |
| Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis). | | | | | | | | |
| Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures). | | | | | | | | |
| Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis. | | | | | | | | |
| Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy. | | | | | | | | |
| Subscript "e": Includes imaging for guidance of trans-rectal biopsy. | | | | | | | | |
| Subscript "f": Includes imaging for guidance of trans-vaginal biopsy. | | | | | | | | |
| Subscript "g": For Adult and Pediatric patients. | | | | | | | | |
| Subscript "h": Includes imaging for Cavernous / Non-Cavernous wounds. | | | | | | | | |

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

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

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 | | | | | | | |
| Endoscopy | | P | P | P | | P | P | P |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (card.) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |
| N = new indication. P = previously cleared in K130247 & K130308 | | | | | | | | |
| 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: _____

**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

Primary Contact Person:
Angela Van Arsdale
R.A. / Q.A. Manager
Telephone: (203) 269-5088 Ext: 346
Fax Number: (203) 269-6075

Manufacturer:
Hitachi Medical Corporation
4-14-1, Soto-Kanda, Chiyoda-Ku,
Tokyo, Japan

Date Prepared: August 7, 2014

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

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

3. Legally Marketed Predicate Device(s):

Hitachi Noblus™ Diagnostic Ultrasound System [K130308]
HI VISION ASCENDUS Diagnostic Ultrasound Scanner [K110673]
Siemens Medical Solutions USA, Inc. [K130881]
Hudson 2060 Ultrasound Scanner [K022928]

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 standard Lithium ion computer battery – to allow for system portability
- 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.), 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 subject device Hitachi Noblus™ Diagnostic Ultrasound device is technically comparable and substantially equivalent to the predicate Hitachi Noblus™ Diagnostic Ultrasound device [K130308]. Both are track 3 systems that incorporate the same fundamental and scientific technologies. The subject system has expanded indications intended use and additional transducers than the predicate system.

The Noblus™ is capable of scanning wounds in the same manner as the predicate Hudson 2020/2040/2060 scanner [K022928]. Wound scanning with the Noblus™ system does not add any additional risk while providing the same supportive evidence in medical diagnosis of disease state as the currently cleared predicate device [K022928].

The Noblus™ free-hand scanning method used for 3D visualization is the same as the Hitachi HI VISION ASCENDUS Diagnostic Ultrasound Scanner cleared via K110673.

The Noblus™ Real Time Tissue Elastography feature incorporates a strain ratio feature, which is substantially equivalent to the Siemen Acuson S2000 and S3000 [K130881] Supersonic Image Shearwave Elastography feature. Both Strain Ratio and Supersonic Image Shearwave provides color graph of tissue strain (hardness of tissue) to assist in visualization of location and perimeter of a tumor, lump or mass in liver, breast, thyroid, etc. for biopsy purposes. The addition of strain ratio to the Noblus™ Real Time Tissue Elastography feature does not add any additional risk. The Elastography Strain Ratio feature provides Physicians additional empirical data that may be used in conjunction with other medical data to assist in clinical diagnosis.

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 Hitachi Aloka Medical, Ltd. Noblus™ Diagnostic Ultrasound scanner is substantially equivalent in safety and effectiveness to the predicate devices;

- The subject and predicate device(s) are both indicated for diagnostic ultrasound imaging and fluid flow analysis.
- The subject and predicate device(s) have the same gray scale and Doppler capabilities.
- The subject and predicate device(s) have the same essential technology for imaging, Doppler functions, and signal processing.
- The subject and predicate device(s) have acoustic level below the Track 3 FDA limits.
- The subject and predicate device(s) are manufactured in accordance to FDA 21 CFR 820 Quality System Regulations.
- The subject and predicate device(s) are designed and manufactured to the same electrical and physical safety standards.
- The subject and predicate device(s) are manufactured with materials that have been tested in accordance to ISO 10993-1; all biocompatibility testing has been conducted in accordance to each component material characterization, type of body contact, and duration contact risk profile.
- The subject and predicate device(s) are designed to be re-usable and provide instructions for cleaning, disinfection, and sterilization in the Ultrasound system and transducer manuals.
- The subject and the predicate K022928 are both safe and effective for wound scanning.
- The subject and the predicate K110673 are both safe and effective for a free-hand scanning method used for 3D visualization
- The subject device is safe and effective with the use of a fully featured Real Time Tissue Elastography (RTTE) inclusive of Strain Ratio. Strain Ratio component of the Noblus™ RTTE is equivalent to the Supersonic Image Shearwave Elastography predicate K130881.

END OF SUMMARY