



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Siemens Medical Solutions USA, Inc.  
% Mr. Mark Job  
Responsible Third Party Official  
Regulatory Technology Services, LLC  
1394 25<sup>th</sup> Street, NW  
BUFFALO MN 55313

August 15, 2017

Re: K172374

Trade/Device Name: ACUSON NX2 Diagnostic Ultrasound System  
ACUSON NX2 Elite Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, ITX

Dated: August 3, 2017

Received: August 7, 2017

Dear Mr. Job:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

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

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

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

Sincerely,

 For

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

Enclosure

## Indications for Use

510(k) Number (if known)

K172374

Device Name

ACUSON NX2 Diagnostic Ultrasound System  
ACUSON NX2 Elite Diagnostic Ultrasound System

Indications for Use (Describe)

The ACUSON NX2 and NX2 Elite diagnostic ultrasound imaging systems are intended for the following applications: Cardiac, Fetal, Abdominal (including liver), Pediatric, Small Parts (Small Organ), Transcranial, OB/GYN, Pelvic, Urology, Vascular (including Peripheral Vessel) and Musculoskeletal applications.

The systems also provide for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

Ultrasound is used as an imaging aid, but may have further restrictions specific to in-vitro fertilization (IVF), chorionic villus sampling (CVS), and percutaneous umbilical cord blood sampling (PUBS) procedures. Observe local laws and regulations.

The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding the state of their cardiovascular system.

Note: This feature can be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Society of Echocardiography Carotid Intima-Media Thickness Task Force. Endorsed by the Society for Vascular Medicine."

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.

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**Diagnostic Ultrasound Indications for Use Form**

510(k) Number (if known):

Device Name:  
 Intended Use:

**ACUSON NX2™ Diagnostic Ultrasound System**  
 Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
Other (Track 1 Only)	Specific (Tracks 1& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	BMDC	
	Abdominal	P	P	P		P	P	BMDC	
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	BMDC	
	Small Organ (Note 1)	P	P	P		P	P	BMDC	
	Neonatal Cephalic								
	Adult Cephalic	P	P	P		P	P	BMDC	
	Trans-rectal	P	P	P		P	P	BMDC	
	Trans-vaginal	P	P	P		P	P	BMDC	
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)	P	P	P		P	P	BMDC	
	Musculo-skel. (Superfic)	P	P	P		P	P	BMDC	
Intra -vascular									
Other (Specify)									
Cardiac	Cardiac Adult	P	P	P	P	P	P	BMDC	
	Cardiac Pediatric	P	P	P	P	P	P	BMDC	
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-Cardiac								
Other (Specify)									
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	BMDC	
	Other (Specify)								

N = new indication; P = previously cleared (K161787)

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.  
 Note 2 For example: abdominal, vascular

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Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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**Diagnostic Ultrasound Indications for Use Form**

510(k) Number (if known):

Device Name:  
 Intended Use:

**ACUSON NX2 Elite Diagnostic Ultrasound System**  
 Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
Other (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal  Imaging & Other	Fetal	N	N	N		N	N	BMDC	
	Abdominal	N	N	N		N	N	BMDC	
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	BMDC	
	Small Organ (Note 1)	N	N	N		N	N	BMDC	
	Neonatal Cephalic								
	Adult Cephalic	N	N	N	N	N	N	BMDC	
	Trans-rectal	N	N	N		N	N	BMDC	
	Trans-vaginal	N	N	N		N	N	BMDC	
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)	N	N	N		N	N	BMDC	
	Musculo-skel. (Superfic)	N	N	N		N	N	BMDC	
Intra -vascular									
Other (Specify)									
Cardiac	Cardiac Adult	N	N	N	N	N	N	BMDC	
	Cardiac Pediatric	N	N	N	N	N	N	BMDC	
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-Cardiac								
Other (Specify)									
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	BMDC	
	Other (Specify)								

N = new indication; P = previously cleared (K161787)

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 2 For example: abdominal, vascular

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**Diagnostic Ultrasound Indications for Use Form**

510(k) Number (if known):

Device Name: **CH5-2 Convex Array Transducer for use with:  
 ACUSON NX2™ Diagnostic Ultrasound System /  
 ACUSON NX2 Elite Diagnostic Ultrasound System**

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
Other (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	BMDC	
	Abdominal	P	P	P		P	P	BMDC	
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	BMDC	
	Small Organ (Note 1)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
Intra-vascular									
Other (Specify)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	BMDC	
	Other (Specify)								

N = new indication; P = previously cleared (K161787)

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.  
 Note 2 For example: abdominal, vascular

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**Diagnostic Ultrasound Indications for Use Form**

510(k) Number (if known):

Device Name: **VF10-5 Linear Array Transducer for use with:  
 ACUSON NX2™ Diagnostic Ultrasound System /  
 ACUSON NX2 Elite Diagnostic Ultrasound System**

Intended Use: **Diagnostic imaging or fluid flow analysis of the human body as follows:**

Clinical Application		Mode of Operation							
Other (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	BMDC	
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	BMDC	
	Small Organ (Note 1)	P	P	P		P	P	BMDC	
	Neonatal Cephalic								
	Adult Cephalic	P	P	P		P	P	BMDC	
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)	P	P	P		P	P	BMDC	
	Musculo-skel. (Superfic)	P	P	P		P	P	BMDC	
	Intra-vascular								
Other (Specify)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	BMDC	
	Other (Specify)								

N = new indication; P = previously cleared (K161787)

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 2 For example: abdominal, vascular

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**Diagnostic Ultrasound Indications for Use Form**

510(k) Number (if known):

Device Name: **C5-2v Convex Array Transducer for use with:  
 ACUSON NX2™ Diagnostic Ultrasound System /  
 ACUSON NX2 Elite Diagnostic Ultrasound System**

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
Other (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	BMDC	
	Abdominal	P	P	P		P	P	BMDC	
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	BMDC	
	Small Organ (Note 1)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
Intra-vascular									
Other (Specify)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	BMDC	
	Other (Specify)								

N = new indication; P = previously cleared (K161787)

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 2 For example: abdominal, vascular

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**Diagnostic Ultrasound Indications for Use Form**

510(k) Number (if known):

Device Name: **L10-5v Linear Array Transducer for use with:  
 ACUSON NX2™ Diagnostic Ultrasound System /  
 ACUSON NX2 Elite Diagnostic Ultrasound System**

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
Other (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	BMDC	
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	BMDC	
	Small Organ (Note 1)	P	P	P		P	P	BMDC	
	Neonatal Cephalic								
	Adult Cephalic	P	P	P		P	P	BMDC	
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)	P	P	P		P	P	BMDC	
	Musculo-skel. (Superfic)	P	P	P		P	P	BMDC	
Intra-vascular									
Other (Specify)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
Other (Specify)									
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	BMDC	
	Other (Specify)								

N = new indication; P = previously cleared (K161787)

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 2 For example: abdominal, vascular

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**Diagnostic Ultrasound Indications for Use Form**

510(k) Number (if known):

Device Name: **EC9-4 Convex Array Transducer for use with:  
 ACUSON NX2™ Diagnostic Ultrasound System /  
 ACUSON NX2 Elite Diagnostic Ultrasound System**

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
Other (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	BMDC	
	Abdominal								
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Note 1)	P	P	P		P	P	BMDC	
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	BMDC	
	Trans-vaginal	P	P	P		P	P	BMDC	
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
Intra-vascular									
Other (Specify)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-Cardiac								
Other (Specify)									
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared (K161787)

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 2 For example: abdominal, vascular

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**Diagnostic Ultrasound Indications for Use Form**

510(k) Number (if known):

Device Name: **P4-2 Phased Sector Array Transducer for use with:  
 ACUSON NX2™ Diagnostic Ultrasound System /  
 ACUSON NX2 Elite Diagnostic Ultrasound System**

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
Other (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	BMDC	
	Abdominal	P	P	P		P	P	BMDC	
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Note 1)	P	P	P		P	P	BMDC	
	Neonatal Cephalic								
	Adult Cephalic	P	P	P		P	P	BMDC	
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
Intra-vascular									
Other (Specify)									
Cardiac	Cardiac Adult	P	P	P	P	P	P	BMDC	
	Cardiac Pediatric	P	P	P	P	P	P	BMDC	
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
Other (Specify)									
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared (K161787)

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.  
 Note 2 For example: abdominal, vascular

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**Diagnostic Ultrasound Indications for Use Form**

510(k) Number (if known):

Device Name: **C8F3 Transducer for use with:  
 ACUSON NX2™ Diagnostic Ultrasound System /  
 ACUSON NX2 Elite Diagnostic Ultrasound System**

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
Other (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	BMDC	
	Abdominal	P	P	P		P	P	BMDC	
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Note 1)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
Other (Specify)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared (K161787)

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.  
 Note 2 For example: abdominal, vascular

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**Diagnostic Ultrasound Indications for Use Form**

510(k) Number (if known):

Device Name: **CW2 Transducer for use with:  
 ACUSON NX2 Elite Diagnostic Ultrasound System**

Intended Use: **Diagnostic imaging or fluid flow analysis of the human body as follows:**

Clinical Application		Mode of Operation							
Other (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Note 1)								
	Neonatal Cephalic								
	Adult Cephalic					P			
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
Other (Specify)									
Cardiac	Cardiac Adult							P	
	Cardiac Pediatric							P	
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
Other (Specify)									
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared (K163635)

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.  
 Note 2 For example: abdominal, vascular

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**Diagnostic Ultrasound Indications for Use Form**

510(k) Number (if known):

Device Name: **CW5 Transducer for use with:  
 ACUSON NX2 Elite Diagnostic Ultrasound System**

Intended Use: **Diagnostic imaging or fluid flow analysis of the human body as follows:**

Clinical Application		Mode of Operation							
Other (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Note 1)								
	Neonatal Cephalic								
	Adult Cephalic					P			
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
Other (Specify)									
Cardiac	Cardiac Adult							P	
	Cardiac Pediatric							P	
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared (K161787)

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.  
 Note 2 For example: abdominal, vascular

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 Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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 Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

510(k) \_\_\_\_\_

**510(k) Summary**

**Date:** June 15, 2017

**Submitter:** Siemens Medical Solutions USA, Inc.,  
Ultrasound Division  
685 East Middlefield Road  
Mountain View, California 94043

**Manufacturing Facility:** Siemens Healthcare Ltd.  
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**Contact Person:** Shelly Pearce  
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**Device Name:** ACUSON NX2 Diagnostic Ultrasound System  
ACUSON NX2 Elite Diagnostic Ultrasound System

**Common Name:** Diagnostic Ultrasound System with Accessories

**Classification:** Regulatory Class: II  
Review Category: Tier II  
Classification Panel: Radiology

Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

**A. Legally Marketed Predicate Devices**

The ACUSON NX2 Elite Diagnostic Ultrasound System is a multi-purpose diagnostic ultrasound system with accessories and proprietary software. It is substantially equivalent to ACUSON NX2 (K161787). It has two more transducers and two more software features compared to ACUSON NX2 (K161787). The two more transducers of ACUSON NX2 Elite are CW2 and CW5 which are

cleared on ACUSON S-family Diagnostic Ultrasound System (K163635). Also, two more software features are Advanced foursight 4D and eSieTouch which are also cleared on ACUSON S-family Diagnostic Ultrasound System (K163635).

## **B. Device Description**

The ACUSON NX2 Elite Diagnostic Ultrasound System is a multi-purpose mobile, software controlled, diagnostic ultrasound systems with an on-screen display for thermal and mechanical indices related to potential bio-effect mechanisms. Its function is to acquire harmonic ultrasound echo data and display it in B-Mode, M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Color M mode, Tissue Doppler Image, Amplitude Doppler Mode, a combination of modes, or Harmonic Imaging and 3D Imaging, or Harmonic Imaging and 4D imaging on a Flat Panel Display.

\* ACUSON NX2 Diagnostic Ultrasound System is exactly same as K161787.

## **C. Intended Use**

The ACUSON NX2 and NX2 Elite diagnostic ultrasound imaging systems are intended for the following applications: Cardiac, Fetal, Abdominal (including liver), Pediatric, Small Parts (Small Organ), Transcranial, OB/GYN, Pelvic, Urology, Vascular (including Peripheral Vessel) and Musculoskeletal applications.

The systems also provide for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

Ultrasound is used as an imaging aid, but may have further restrictions specific to in-vitro fertilization (IVF), chorionic villus sampling (CVS), and percutaneous umbilical cord blood sampling (PUBS) procedures. Observe local laws and regulations.

The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding the state of their cardiovascular system.

Note: This feature can be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Society of Echocardiography Carotid Intima-Media Thickness Task Force. Endorsed by the Society for Vascular Medicine."

## **D. Substantial Equivalence**

The ACUSON NX2 Elite Diagnostic Ultrasound System is a multi-purpose diagnostic ultrasound system with accessories and proprietary software. It is substantially equivalent to ACUSON NX2 (K161787). It has two more transducers and two more software features compared to ACUSON NX2 (K161787). The two more transducers of ACUSON NX2 Elite are CW2 and CW5 which are cleared on ACUSON S-family Diagnostic Ultrasound System (K163635). Also, two more software features are Advanced foursight 4D and eSieTouch which are also cleared on



ACUSON S-family Diagnostic Ultrasound System (K163635). All systems transmit ultrasonic energy into patients, and then perform post processing of received echoes to generate onscreen display of anatomic structures and fluid flow within the body. All systems allow for specialized measurements of structures and flow, and calculations.

The submission device is substantially equivalent to the predicate with regard to both intended use and technological characteristics.

Feature / Characteristic	Predicate Device ACUSON S-family (K163635)	Predicate Device ACUSON NX2™ (K161787)	Submission Device ACUSON NX2 Elite
▪ Fetal Echo	√	√	√
▪ Abdominal	√	√	√
▪ Renal	√	√	√
▪ Cerebrovascular	√	√	√
▪ Orthopedics	√	√	√
▪ Small Organ	√	√	√
▪ Pediatric	√	√	√
▪ Adult Cephalic	√	√	√
▪ Cardiac (Adult)	√	√	√
▪ Intracardiac	√	-	-
▪ Trans-esophageal	√	√	√
▪ Transrectal	√	√	√
▪ Urology	√	√	√
▪ Transvaginal	√	√	√
▪ Peripheral vessel	√	√	√
▪ Musculo-skeletal (conventional)	√	√	√
▪ Musculo-skeletal (superficial)	√	√	√
▪ Emergency Medicine	√	√	√
▪ 2.0 MHz	√	√	√
▪ 2.5 MHz	√	√	√
▪ 3.0 MHz	√	√	√
▪ 3.5 MHz	√	√	√
▪ 4.0 MHz	√	√	√
▪ 5.0 MHz	√	√	√
▪ 5.5 MHz	√	√	√
▪ 6.0 MHz	√	√	√
▪ 6.5 MHz	√	√	√
▪ 7.5 MHz	√	√	√
▪ 8.0 MHz	√	√	√
▪ 9.0 MHz	√	√	√
▪ 10.0 MHz	√	√	√
▪ 11.0 MHz	√	-	-
▪ B	√	√	√

Feature / Characteristic	Predicate Device ACUSON S-family (K163635)	Predicate Device ACUSON NX2™ (K161787)	Submission Device ACUSON NX2 Elite
▪ M	√	√	√
▪ PWD (Pulsed Wave Doppler)	√	√	√
▪ CWD (Continuous Wave Doppler)	√	-	√
▪ SCW (Steerable CW)	√	√	√
▪ CD (Color Doppler)	√	√	√
▪ Amplitude Doppler (Power Doppler)	√	√	√
▪ Directional Power Doppler	√	√	√
▪ Combined (BM, BC, BCM, BCD)	√	√	√
▪ THI (Tissue Harmonic Imaging)	√	√	√
▪ AMM (Anatomical M-mode)	√	√	√
▪ Doppler Tissue Image (Color, PW)	√	-	√
▪ M-THI	√	√	√
▪ US Security (Virus Protection)	√	√	√
▪ Multi-View Spatial Compounding (SieClear)	√	√	√
▪ Advanced *SieClear (*SieClear = Multi-View Spatial Compounding)	√	√	√
▪ DTCE (Dynamic Tissue Contrast Enhancement)	√	√	√
▪ TGO (Tissue Grayscale Optimization)	√	√	√
▪ HD Zoom	-	√	√
▪ DICOM (3.0 connectivity, Worklist, MPPS)	√	√	√
▪ DICOM SR OB/GYN	√	√	√
▪ DICOM SR Cardiac	√	√	√
▪ DICOM SR Vascular	√	√	√
▪ 3D Imaging (3-Scape)	√	√	√
▪ 3D Measurements	√	√	√
▪ 4D Basic Imaging (fourSight 4D)	√	√	√
▪ Panoramic 2D Imaging	√	√	√
▪ Syngo Auto OB	√	√	√
▪ Stress Echo	√	√	√
▪ Vascular Enhancement (Clarify VE)	√	√	√
▪ VET(Pictogram)	-	√	√
▪ Auto Left Heart	√	√	√
▪ Syngo AHP (Arterial Health Package)	√	√	√
▪ Advanced fourSight 4D	√	-	√
▪ eSieTouch	√	-	√
▪ Monitor: FPD	√ (21" FPD)	√ (21.5" FPD)	√ (21.5" FPD)

Feature / Characteristic	Predicate Device ACUSON S-family (K163635)	Predicate Device ACUSON NX2™ (K161787)	Submission Device ACUSON NX2 Elite
▪ Wireless	√	√	√

**E. A brief discussion of nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence**

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic and mechanical safety and have been found to conform with applicable medical device safety standards. The systems comply with the following voluntary standards:

- AAMI/ANSI ES 60601-1, Safety Requirements for Medical Equipment
- IEC 60601-2-37 Diagnostic Ultrasound Safety Standards
- AIUM/NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound
- IEC 62359, Test methods for the determination of thermal and mechanical indices
- Safety and EMC Requirements for Medical Equipment
  - IEC 60601-1-2
  - IEC 60601-2-18
- ISO 10993-1 Biocompatibility

\* ACUSON NX2 Diagnostic Ultrasound System is exactly same as K161787.

**F. A summary discussion of the clinical tests submitted, referenced, or relied on for a determination of substantial equivalence.**

Since the ACUSON NX2 Elite Diagnostic Ultrasound Systems uses the same technology and principles as existing devices, clinical data is not required.

\* ACUSON NX2 Diagnostic Ultrasound System is exactly same as K161787.

**G. Summary**

Intended uses and other key features are consistent with traditional clinical practice and FDA guidelines. The design and development process of the manufacturer conforms to 21 CFR 820 Quality System Regulation and ISO 13485:2003 quality system standards. The product is designed to conform to applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound system has accumulated a long history of safe and effective performance. Therefore, it is the opinion of Siemens Medical Solutions USA, Inc. that the ACUSON NX2 Elite Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

The ACUSON NX2 Elite Diagnostic Ultrasound System is verified and validated according to the company's design control process.

\* ACUSON NX2 Diagnostic Ultrasound System is exactly same as K161787.