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

July 28, 2016

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

Re: K161787
Trade/Device Name: ACUSON NX2™ Diagnostic Ultrasound Systems
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: June 27, 2016
Received: June 29, 2016

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 yours,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K161787

Device Name
ACUSON NX2 Diagnostic Ultrasound System

Indications for Use *(Describe)*
The ACUSON NX2TM ultrasound imaging system is 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.

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

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PRAStaff@fda.hhs.gov

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

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

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

Clinical Application		**Mode of Operation**							
Other (Track1 Only)	Specific (Tracks1l& 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	Note 2,3,4,5 ,6,8,9,11,13
	Abdominal	N	N	N		N	N	BMDC	Note 2,3,4,5,6,8,9,13
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	BMDC	Note 2,3,4,5,6,8,9
	SmallOrgan (Note 1)	N	N	N		N	N	BMDC	Note 2,3,4,5,6,8,9
	Neonatal Cephalic								
	Adult Cephalic	N	N	N	N	N	N	BMDC	Note 2,3,4,5,6,8,9,10
	Trans-rectal	N	N	N		N	N	BMDC	Note 2,3,4,5,6,8,9
	Trans-vaginal	N	N	N		N	N	BMDC	Note 2,3,4,5,6,8,9,11,
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)	N	N	N		N	N	BMDC	Note 2,3,4,6,8,9,
	Musculo-skel. (Superfic)	N	N	N		N	N	BMDC	Note 2,3,4,6,8,9
	Intra -vascular								
	Other (Specify)								
Cardiac	Cardiac Adult	N	N	N		N	N	BMDC	Note 2,3,4,6,7,8,12
	Cardiac Pediatric	N	N	N		N	N	BMDC	Note 2,3,4,6,8,12
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-Cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	BMDC	Note 2,3,4,6,8,9
	Other (Specify)								

N = new indication; P = previously cleared

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 SieClear
Note 4 Advanced SieClear
Note 5 3-Scape 3D Imaging
Note 6 For example: abdominal, vascular
Note 7 Stress Echo Imaging
Note 8 Clarify Vascular Enhancement Technology
Note 9 SieScape Panoramic Imaging
Note 10 syngo Arterial Health Package (AHP)
Note 11 syngo Auto OB Measurements
Note 12 syngo Auto Left Heart (Auto LH) Technology
Note 13 syngo fourSight 4D imaging

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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)

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

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

Clinical Application		**Mode of Operation**							
Other (Track1 Only)	Specific (Tracks1I& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
	Fetal	P	P	P		P	P	BMDC	Note 2,3,4,5,6,8,9,11
	Abdominal	P	P	P		P	P	BMDC	Note 2,3,4,5,6,8,9
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
Fetal	Pediatric	P	P	P		P	P	BMDC	Note 2,3,4,5,6,8,9
Imaging & Other	SmallOrgan (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	Note 2,3,4,6,8,9
	Other (Specify)								

N = new indication; P = previously cleared by K152469

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 SieClear
Note 4 Advanced SieClear
Note 5 3-Scape 3D Imaging
Note 6 For example: abdominal, vascular
Note 7 Stress Echo Imaging
Note 8 Clarify Vascular Enhancement Technology
Note 9 SieScape Panoramic Imaging
Note 10 syngo Arterial Health Package (AHP)
Note 11 syngo Auto OB Measurements
Note 12 syngo Auto Left Heart (Auto LH) Technology
Note 13 syngo fourSight 4D imaging

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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)

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

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

Clinical Application		**Mode of Operation**							
Other (Track1 Only)	Specific (Tracks1l& 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	Note 2,3,4,6,8,9
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	BMDC	Note 2,3,4,6,8,9
	SmallOrgan (Note 1)	P	P	P		P	P	BMDC	Note 2,3,4,6,8,9
	Neonatal Cephalic								
	Adult Cephalic	P	P	P		P	P	BMDC	Note 2,3,4,6,8,9,10
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)	P	P	P		P	P	BMDC	Note 2,3,4,6,8,9
	Musculo-skel. (Superfic)	P	P	P		P	P	BMDC	Note 2,3,4,6,8,9
	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	Note 2,3,4,8,9
	Other (Specify)								

N = new indication; P = previously cleared by K152469

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 SieClear
Note 4 Advanced SieClear
Note 5 3-Scape 3D Imaging
Note 6 For example: abdominal, vascular
Note 7 Stress Echo Imaging
Note 8 Clarify Vascular Enhancement Technology
Note 9 SieScape Panoramic Imaging
Note 10 syngo Arterial Health Package (AHP)
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Note 12 syngo Auto Left Heart (Auto LH) Technology
Note 13 syngo fourSight 4D imaging

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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)_____

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

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

Clinical Application		**Mode of Operation**							
Other (Track1 Only)	Specific (Tracks1l& 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	Note 2,3,4,5,6,8,9,11
	Abdominal	N	N	N		N	N	BMDC	Note 2,3,4,5,6,8,9
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	BMDC	Note 2,3,4,5,6,8,9
	SmallOrgan (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	N	N	N		N	N	BMDC	Note 2,3,4,6,8,9
	Other (Specify)								

N = new indication; P = previously cleared

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 SieClear
Note 4 Advanced SieClear
Note 5 3-Scape 3D Imaging
Note 6 For example: abdominal, vascular
Note 7 Stress Echo Imaging
Note 8 Clarify Vascular Enhancement Technology
Note 9 SieScape Panoramic Imaging
Note 10 syngo Arterial Health Package (AHP)
Note 11 syngo Auto OB Measurements
Note 12 syngo Auto Left Heart (Auto LH) Technology
Note 13 syngo fourSight 4D imaging

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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)

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

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

Clinical Application		**Mode of Operation**							
Other (Track1 Only)	Specific (Tracks1l& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N		N	N	BMDC	Note 2,3,4,8,9
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	BMDC	Note 2,3,4,8,9
	SmallOrgan (Note 1)	N	N	N		N	N	BMDC	Note 2,3,4,8,9
	Neonatal Cephalic								
	Adult Cephalic	N	N	N		N	N	BMDC	Note 2,3,4,8,9,10
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)	N	N	N		N	N	BMDC	Note 2,3,4,8,9
	Musculo-skel. (Superfic)	N	N	N		N	N	BMDC	Note 2,3,4,8,9
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	BMDC	Note 2,3,4,8,9
	Other (Specify)								

N = new indication; P = previously cleared

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 SieClear
Note 4 Advanced SieClear
Note 5 3-Scape 3D Imaging
Note 6 For example: abdominal, vascular
Note 7 Stress Echo Imaging
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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)

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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

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

Clinical Application		**Mode of Operation**							
Other (Track1 Only)	Specific (Tracks1l& 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	Note 2,3,4,5,6,8,9,11
	Abdominal								
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	SmallOrgan (Note 1)	P	P	P		P	P	BMDC	Note 2,3,4,5,8,9
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	BMDC	Note 2,3,4,5,6,8,9
	Trans-vaginal	P	P	P		P	P	BMDC	Note 2,3,4,5,6,8,9,11
	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 by K152469

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 SieClear
Note 4 Advanced SieClear
Note 5 3-Scape 3D Imaging
Note 6 For example: abdominal, vascular
Note 7 Stress Echo Imaging
Note 8 Clarify Vascular Enhancement Technology
Note 9 SieScape Panoramic Imaging
Note 10 syngo Arterial Health Package (AHP)
Note 11 syngo Auto OB Measurements
Note 12 syngo Auto Left Heart (Auto LH) Technology
Note 13 syngo fourSight 4D imaging

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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)

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

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

Clinical Application		**Mode of Operation**							
Other (Track1 Only)	Specific (Tracks1l& 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	Note 2,8
	Abdominal	P	P	P		P	P	BMDC	Note 2,8
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	SmallOrgan (Note 1)	P	P	P		P	P	BMDC	Note 2,8
	Neonatal Cephalic								
	Adult Cephalic	P	P	P		P	P	BMDC	Note 2,8
	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	Note 2,3,4,6,7,8,12
	Cardiac Pediatric	P	P	P	P	P	P	BMDC	Note 2,3,4,6, 8,12
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared by K152469

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 SieClear
Note 4 Advanced SieClear
Note 5 3-Scape 3D Imaging
Note 6 For example: abdominal, vascular
Note 7 Stress Echo Imaging
Note 8 Clarify Vascular Enhancement Technology
Note 9 SieScape Panoramic Imaging
Note 10 syngo Arterial Health Package (AHP)
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Note 12 syngo Auto Left Heart (Auto LH) Technology
Note 13 syngo fourSight 4D imaging

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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)

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

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

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

Clinical Application		**Mode of Operation**							
Other (Track1 Only)	Specific (Tracks1I& 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	Note 2,3,4,5,6,8,9,11,13
	Abdominal	P	P	P		P	P	BMDC	Note 2,3,4,5,6,8,9,13
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	SmallOrgan (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 by K152469

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 SieClear
Note 4 Advanced SieClear
Note 5 3-Scape 3D Imaging
Note 6 For example: abdominal, vascular
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Note 10 syngo Arterial Health Package (AHP)
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Note 12 syngo Auto Left Heart (Auto LH) Technology
Note 13 syngo fourSight 4D imaging

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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: May 14, 2016

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

Manufacturing Facility: Siemens Healthcare Ltd.
2nd -3rd floor, 143, Sunhwan-ro,
Jungwon-gu, Seongnam-si, Gyeonggi-do,
Republic of Korea

Contact Person: Shelly Pearce
Tel: (650) 279-0134

Device Name: ACUSON NX2™ 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™ Diagnostic Ultrasound System is a multi-purpose diagnostic ultrasound system with accessories and proprietary software, and is substantially equivalent to our current products, the ACUSON X700™ Diagnostic Ultrasound System (K141846) and ACUSON NX3™ Diagnostic Ultrasound System (K152469).

B. Device Description

The ACUSON NX2™ 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.

C. Intended Use

The ACUSON NX2™ ultrasound imaging system is 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™ Diagnostic Ultrasound System is a multi-purpose diagnostic ultrasound system with accessories and proprietary software, and is substantially equivalent to our current products, the ACUSON X700™ Diagnostic Ultrasound System (K141846), and ACUSON NX3™ Diagnostic Ultrasound System (K152469). 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 X700™ (K141846)	Predicate Device ACUSON NX3™ (K152469)	Submission Device ACUSON NX2™
Indications for Use:			
■ Fetal Echo	√	√	√
■ Abdominal	√	√	√
■ Renal	√	√	√
■ Cerebrovascular	√	√	√
■ Orthopedics	√	√	√
■ Small Organ	√	√	√
■ Pediatric	√	√	√
■ Adult Cephalic	√	√	√
■ Cardiac (Adult)	√	√	√
■ Intracardiac	√	-	-
■ Trans-esophageal	√	√	√
■ Transrectal	√	√	√
■ Urolology	√	√	√
■ Transvaginal	√	√	√
■ Peripheral vessel	√	√	√
■ Musculo-skeletal (conventional)	√	√	√
■ Musculo-skeletal (superficial)	√	√	√
■ Emergency Medicine	√	√	√
Center Frequencies Supported:			
■ 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	√	√	-
■ 12.0 MHz	√	-	-
■ 13.0 MHz	√	-	-
Modes:			
■ B	√	√	√
■ M	√	√	√
■ PWD (Pulsed Wave Doppler)	√	√	√
■ CWD (Continuous Wave Doppler)	√	-	-
■ SCW (Steerable CW)	√	√	√

Feature / Characteristic	Predicate Device ACUSON X700™ (K141846)	Predicate Device ACUSON NX3™ (K152469)	Submission Device ACUSON NX2™
▪ 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	√	√	√
Features:			
▪ 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)	√	-	√
▪ Monitor: FPD	**√ (20" FPD)**	**√ (21.5" FPD)**	**√ (21.5" FPD)**
▪ 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 to applicable medical device safety standards. The systems comply with the following voluntary standards:

- UL 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

Patient contact materials, electrical and mechanical safety are unchanged from the predicate devices.

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

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

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™ Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

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