Siemens Medical Solutions, USA, Inc.
% Mr. Prithul Bom
Official Correspondent
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite #510k
SAINT PAUL MN 55114

October 22, 2019

Re: K192835
Trade/Device Name: ACUSON NX3 Diagnostic Ultrasound System / ACUSON NX3 Elite Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: October 1, 2019
Received: October 2, 2019

Dear Mr. Bom:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192835

Device Name
ACUSON NX3 Diagnostic Ultrasound System
ACUSON NX3 Elite Diagnostic Ultrasound System

Indications for Use *(Describe)*

For ACUSON NX3

The ACUSON NX3 ultrasound imaging system is intended for the following applications: Fetal Abdominal (including liver), Pediatric, Small Parts (Small Organ), Neonatal Cephalic, Adult Cephalic, Transcranial, OB/GYN, Pelvic, Neonatal, Cardiac, Vascular (including Peripheral Vessel), Musculoskeletal, Superficial Musculoskeletal and Urology 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.

For ACUSON NX3 Elite

The ACUSON NX3 Elite ultrasound imaging system is intended for the following applications: Fetal, Abdominal (including liver, intra-operative), Pediatric, Small Parts (Small Organ including intra-operative), Neonatal Cephalic, Adult Cephalic, Transcranial, OB/GYN, Pelvic, Neonatal, Cardiac(including Transesophageal), Vascular (including Peripheral Vessel, intra-operative), Musculoskeletal, Superficial Musculoskeletal and Urology 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.

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 state of their cardiovascular system.

Note: This feature should 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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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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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

510(k) Number (if known):

Device Name: **ACUSON NX3 Elite™ 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 (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	
	Abdominal	P	P	P		P	P	P	
	Intra-operative (Note 2)	P	P	P		P	P	P	
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	
	SmallOrgan (Note 1)	P	P	P		P	P	P	
	Neonatal Cephalic	P	P	P		P	P	P	
	Adult Cephalic	P	P	P	P	P	P	P	
	Trans-rectal	P	P	P		P	P	P	
	Trans-vaginal	P	P	P		P	P	P	
	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 -vascular								
	Other (Specify)								
Cardiac	Cardiac Adult	P	P	P	P	P	P	P	
	Cardiac Pediatric	P	P	P	P	P	P	P	
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)	P	P	P	P	P	P	P	
	Intra-Cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P	
	Other (Specify)								

N = new indication; P = previously cleared by (K173957)

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 For example: abdominal, vascular
Note 3 Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M

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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: **ACUSON NX3™ 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 (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	
	Abdominal	P	P	P		P	P	P	
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	
	SmallOrgan (Note 1)	P	P	P		P	P	P	
	Neonatal Cephalic	P	P	P		P	P	P	
	Adult Cephalic	P	P	P		P	P	P	
	Trans-rectal	P	P	P		P	P	P	
	Trans-vaginal	P	P	P		P	P	P	
	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 -vascular								
	Other (Specify)								
Cardiac	Cardiac Adult	P	P	P		P	P	P	
	Cardiac Pediatric	P	P	P		P	P	P	
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-Cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P	
	Other (Specify)								

N = new indication; P = previously cleared by (K173957)

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 For example: abdominal, vascular
Note 3 Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M

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

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** Transducer for use with:
ACUSON NX3 Elite™ Diagnostic Ultrasound System / ACUSON NX3™ 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 (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	
	Abdominal	P	P	P		P	P	P	
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	
	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	P	
	Other (Specify)								

N = new indication; P = previously cleared by (K173957)

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 For example: abdominal, vascular
Note 3 Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M

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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 NX3 Elite™ Diagnostic Ultrasound System / ACUSON NX3™ 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 (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	
	SmallOrgan (Note 1)	P	P	P		P	P	P	
	Neonatal Cephalic								
	Adult Cephalic	P	P	P		P	P	P	
	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-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	P	
	Other (Specify)								

N = new indication; P = previously cleared by (K173957)

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 For example: abdominal, vascular
Note 3 Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M

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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: **VF12-4** Linear Array Transducer for use with:
ACUSON NX3 Elite™ Diagnostic Ultrasound System / ACUSON NX3™ 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 (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	
	SmallOrgan (Note 1)	P	P	P		P	P	P	
	Neonatal Cephalic **– NX3 Elite only**	P	P	P		P	P	P	
	Adult Cephalic	P	P	P		P	P	P	
	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-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	P	
	Other (Specify)								

N = new indication; P = previously cleared by (K173957)

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 For example: abdominal, vascular
Note 3 Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M

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

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

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **EC10-5w** Convex Array Transducer for use with:
ACUSON NX3 Elite™ 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 (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	
	Abdominal								
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	SmallOrgan (Note 1)	P	P	P		P	P	P	
	Neonatal Cephalic	P	P	P		P	P	P	
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	P	
	Trans-vaginal	P	P	P		P	P	P	
	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 (K173957)

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 For example: abdominal, vascular
Note 3 Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M

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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: **EC9-4** Convex Array Transducer for use with:
ACUSON NX3 Elite™ Diagnostic Ultrasound System / ACUSON NX3™ 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 (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	
	Abdominal								
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	SmallOrgan (Note 1)	P	P	P		P	P	P	
	Neonatal Cephalic – **NX3 Elite Only**	P	P	P		P	P	P	
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	P	
	Trans-vaginal	P	P	P		P	P	P	
	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 (K173957)

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 For example: abdominal, vascular
Note 3 Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M

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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: **CW2** Continuous Wave Doppler Transducer for use with:
ACUSON NX3 Elite™ 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 (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Note 2)								
	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				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 by (K173957)

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 For example: abdominal, vascular
Note 3 Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M

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

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

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **CW5** Continuous Wave Doppler Transducer for use with: **ACUSON NX3 Elite™ 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 (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	SmallOrgan (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 by (K173957)

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 For example: abdominal, vascular
Note 3 Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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

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: **P4-2** Phased Sector Array Transducer for use with:
ACUSON NX3 Elite™ Diagnostic Ultrasound System / ACUSON NX3™ 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 (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	
	Abdominal	P	P	P		P	P	P	
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	
	SmallOrgan (Note 1)	P	P	P		P	P	P	
	Neonatal Cephalic **– NX3 Elite Only**	P	P	P		P	P	P	
	Adult Cephalic	P	P	P		P	P	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	P	P	P	P	P	P	
	Cardiac Pediatric	P	P	P	P	P	P	P	
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared by (K173957)

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 For example: abdominal, vascular
Note 3 Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M

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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: **VF16-5** Transducer for use with:
ACUSON NX3 Elite™ 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 (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	
	SmallOrgan (Note 1)	P	P	P		P	P	P	
	Neonatal Cephalic								
	Adult Cephalic	P	P	P		P	P	P	
	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-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 (K173957)

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 For example: abdominal, vascular
Note 3 Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **VF13-5sp** Transducer for use with:
ACUSON NX3 Elite™ 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 (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Note 2)	P	P	P		P	P	P	
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	
	SmallOrgan (Note 1)	P	P	P		P	P	P	
	Neonatal Cephalic								
	Adult Cephalic	P	P	P		P	P	P	
	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-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel (Note 1)	P	P	P		P	P		
	Other (Specify)								

N = new indication; P = previously cleared by (K173957)

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 For example: abdominal, vascular, small parts
Note 3 Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M

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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 NX3 Elite™ Diagnostic Ultrasound System / ACUSON NX3™ 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 (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	
	Abdominal	P	P	P		P	P	P	
	Intra-operative (Note 2)								
	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 (K173957)

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 For example: abdominal, vascular
Note 3 Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **C8-5** Transducer for use with:
ACUSON NX3 Elite™ 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 (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	
	SmallOrgan (Note 1)								
	Neonatal Cephalic	P	P	P		P	P	P	
	Adult Cephalic	P	P	P		P	P	P	
	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	P	P	P		P	P	P	
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared by (K173957)

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 For example: abdominal, vascular
Note 3 Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **P8-4** Transducer for use with:
ACUSON NX3 Elite™ 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 (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	
	SmallOrgan (Note 1)								
	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-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	P	P	P		P	P	P	
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared by (K173957)

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 For example: abdominal, vascular
Note 3 Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **11L4** Transducer for use with:
ACUSON NX3 Elite™ Diagnostic Ultrasound System /
ACUSON NX3™ 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 (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	
	SmallOrgan (Note 1)	P	P	P		P	P	P	
	Neonatal Cephalic								
	Adult Cephalic	P	P	P		P	P	P	
	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-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	P	
	Other (Specify)								

N = new indication; P = previously cleared by (K173957)

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 For example: abdominal, vascular
Note 3 Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **10MC3** Transducer for use with:
ACUSON NX3 Elite™ Diagnostic Ultrasound System /
ACUSON NX3™ 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 (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	
	Abdominal								
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	SmallOrgan (Note 1)	P	P	P		P	P	P	
	Neonatal Cephalic	P	P	P		P	P	P	
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	P	
	Trans-vaginal	P	P	P		P	P	P	
	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 (K173957)

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 For example: abdominal, vascular
Note 3 Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **BP10-3** Transducer for use with:
ACUSON NX3 Elite™ Diagnostic Ultrasound System /
ACUSON NX3™ 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 (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	SmallOrgan (Note 1)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	P	
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-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 (K173957)

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 For example: abdominal, vascular
Note 3 Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M

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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: **V5Ms** Transducer for use with:
ACUSON NX3 Elite™ 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 (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Note 2)								
	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)	P	P	P	P	P	P	P	
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared by (K173957)

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 For example: abdominal, vascular
Note 3 Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M

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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) Summary K192835

Date: August 25, 2019

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

Contact Person:
Hyunjung Lee
Tel: (425) 281-5061

2. Device Name:
ACUSON NX3 Diagnostic Ultrasound System
ACUSON NX3 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

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

3. Legally Marketed Predicate Devices

The ACUSON NX3 Elite Diagnostic Ultrasound System and ACUSON NX3 Diagnostic Ultrasound System are multi-purpose diagnostic ultrasound systems with accessories and proprietary software, and are substantially equivalent to our current product, ACUSON NX3 and ACUSON NX3 Elite Diagnostic Ultrasound System (K173957).

4. Device Description

The ACUSON NX3 Elite and ACUSON NX3 Diagnostic Ultrasound Systems are a multi-purpose mobile, software controlled, diagnostic ultrasound system with an on-screen display of thermal and mechanical indices related to potential bio-effect mechanisms. Its function is to transmit and receive 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, Doppler Tissue Mode, Amplitude Doppler Mode, a combination of modes and Harmonic Imaging and 3D Imaging, or Harmonic Imaging and 4D imaging on a Flat Panel Display.

5. Intended Use/ Indications for use

For ACUSON NX3
The ACUSON NX3 ultrasound imaging system is intended for the following applications: Fetal Abdominal (including liver), Pediatric, Small Parts (Small Organ), Neonatal Cephalic, Adult Cephalic, Transcranial, OB/GYN, Pelvic, Neonatal, Cardiac, Vascular (including Peripheral Vessel), Musculoskeletal, Superficial Musculoskeletal and Urology 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.

For ACUSON NX3 Elite
The ACUSON NX3 Elite ultrasound imaging system is intended for the following applications: Fetal, Abdominal (including liver, intra-operative), Pediatric, Small Parts (Small Organ including intra-operative), Neonatal Cephalic, Adult Cephalic, Transcranial, OB/GYN, Pelvic, Neonatal, Cardiac(including Transesophageal), Vascular (including Peripheral Vessel, intra-operative), Musculoskeletal, Superficial Musculoskeletal and Urology 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.

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 state of their cardiovascular system.

Note: This feature should 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.”.

6. Summary of Technological Characteristics

The ACUSON NX3 Elite and ACUSON NX3 Diagnostic Ultrasound Systems are multi-purpose diagnostic ultrasound systems with accessories and proprietary software, and are substantially equivalent to our current products, the ACUSON NX3 and ACUSON NX3 Elite Diagnostic Ultrasound System (K173957). 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 devices are substantially equivalent to the predicate with regard to both intended use and technological characteristics.

Feature / Characteristic	Predicate Device ACUSON NX3™ (K173957)	Predicate Device ACUSON NX3 Elite™ (K173957)	Submission Device ACUSON NX3	Submission Device ACUSON NX3 Elite
Indications for Use:				
■ Fetal Echo	√	√	√	√
■ Abdominal	√	√	√	√
■ Intra-operative	-	√	-	√
■ Neonatal Cephalic	-	√	-	√
■ Small Organ(parts)	√	√	√	√
■ Pediatric	√	√	√	√
■ Adult Cephalic (Trans-cranial)	√	√	√	√
■ Cardiac (Adult)	√	√	√	√
■ Cardiac (Pediatric)	√	√	√	√
■ Intracardiac	-	-	-	-
■ Trans-esophageal	-	√	-	√
■ Trans-rectal	√	√	√	√
■ Trans-vaginal	√	√	√	√
■ Peripheral vessel	√	√	√	√
■ Musculo-skeletal (conventional)	√	√	√	√
■ Musculo-skeletal (superficial)	√	√	√	√
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	√	√	√	√

Feature / Characteristic	Predicate Device ACUSON NX3™ (K173957)	Predicate Device ACUSON NX3 Elite™ (K173957)	Submission Device ACUSON NX3	Submission Device ACUSON NX3 Elite
■ 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	√	√	√	√
Features:				
■ Multi-View Spatial Compounding (SieClear)	√	√	√	√
■ Advanced SieClear	√	√	√	√
■ DTCE (Dynamic Tissue Contrast Enhancement)	√	√	√	√
■ Tissue Grayscale Optimization (TGO)	√	√	√	√
■ Dual-Beam Processing	√	√	√	√
■ Quad-Beam Processing	√	√	√	√
■ Clip Capture	√	√	√	√
■ 3D Imaging (3-Scape 3D)	√	√	√	√
■ 3D Measurements	√	√	√	√
■ 4D Basic Imaging (fourSight 4D)	√	√	√	√
■ Panoramic 2D Imaging (SieScape)	√	√	√	√
■ Syngo Auto OB	√	√	√	√
■ Syngo Auto Follicle	√	√	√	√
■ Cardiac Imaging physiological signal display multiplane TEE fourSight TEE Imaging	-	√	-	√
■ Stress Echo	√	√	√	√
■ Vascular Enhancement (Clarify VE)	√	√	√	√
■ Syngo VVI (Velocity Vector Image)	√	√	√	√
■ Syngo Auto Left Heart (Auto LH)	-	√	-	√
■ Axius EF	√	√	√	√

Feature / Characteristic	Predicate Device ACUSON NX3™ (K173957)	Predicate Device ACUSON NX3 Elite™ (K173957)	Submission Device ACUSON NX3	Submission Device ACUSON NX3 Elite
▪ Syngo AHP	-	√	-	√
▪ Contrast Agent Image	-	√	-	√
▪ Advanced fourSight 4D	-	√	-	√
▪ DIMAQ	√	√	√	√
▪ Multiple Frequency Imaging(MultiHertz)	√	√	√	√
▪ syngo Mitral Valve Assessments (MVA)	-	√	-	√
▪ Digital Architecture	√	√	√	√
▪ HD Zoom	√	√	√	√
▪ Fully integrated DICOM	√	√	√	√
▪ Monitor: FPD	√ (21.5" FPD)	√ (21.5" FPD)	√ (21.5" FPD)	√ (21.5" FPD)
▪ Wireless	√	√	√	√
▪ eSie Touch	-	√	-	√
# Channels	64	64	64	64
Output Display Standard (Track 3)	√	√	√	√
Patient Contact Materials	Tested to ISO 10993-1	Tested to ISO 10993-1	Tested to ISO 10993-1	Tested to ISO 10993-1
UL60601-1 Certified	√	√	√	√

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

The devices have 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:

- AIUM/NEMA UD-3:2004, Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2:2004 (R2009), Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3
- IEC 62359:2010, Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields / This document and its separate amendments continue to be valid together with the consolidated version.
- Safety and EMC Requirements for Medical Equipment
    - AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)
    - IEC 60601-1:2005, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance / This document and its separate amendments continue to be valid together with the consolidated version

- IEC 60601-1-2 Edition 4.0 2014-02, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-2-18: Edition 3.0 2009-08, Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- IEC 60601-2-37 Edition 2.1 2015, Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

- ISO 10993-1 Fourth edition 2009-10-15, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process [Including: Technical Corrigendum 1 (2010)]

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

Since the ACUSON NX3 Elite and ACUSON NX3 Diagnostic Ultrasound Systems use the same technology and principles as existing devices, clinical data is not required.

9. Summary

This submission expands the Indications for Use from “cardiac” to “cardiac (including transesophageal)”. The submission also adds “small parts” to the intra-operative clinical application of the VF13-5sp transducer. The cardiac (including transesophageal) clinical application was cleared in the V5Ms transducer with the predicate device. The small parts clinical application was also already cleared in the predicate device but not included in the Indications for Use of the VF13-5sp transducer. With this submission, Siemens intends to merely update the Indications for Use of the ACUSON NX3/ELITE and the Indications for Use of the VF13-5sp transducer, both of which were already cleared through the predicate. Other than the updates described in this paragraph, there has been no system or software modification to the subject device. The predicate device and subject device are the same.

Intended uses and other key features are consistent with traditional clinical practice and FDA guidelines. The design and development process of the manufacturer conforms with 21 CFR 820 Quality System Regulation and ISO 13485 quality system standards. The products are designed to conform with 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 that the ACUSON NX3 Elite and ACUSON NX3 Diagnostic Ultrasound Systems are substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

The ACUSON NX3 Elite and ACUSON NX3 Diagnostic Ultrasound Systems are verified and validated according to the company’s design control process.