Toshiba Medical Systems Corporation
% Orlando Tadeo, Jr.
Manager, Regulatory Affairs
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
TUSTIN CA 92780

April 20, 2018

Re: K173962
Trade/Device Name: Viamo c100 TUS-VC100 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: March 22, 2018
Received: March 23, 2018

Dear Mr. Tadeo:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara 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)*

K173962

Device Name
Viamo c100 TUS-VC100 Diagnostic Ultrasound System

Indications for Use *(Describe)*

The **Diagnostic Ultrasound System Viamo c100 Model TUS-VC100** is indicated for the visualization of structures, and dynamic processes with the human body using ultrasound and to provide image information for diagnosis in the following clinical applications: fetal, abdominal, pediatric, small organs (breast, thyroid, testes), transvaginal, trans-rectal, neonatal cephalic, adult cephalic, cardiac (adult, pediatric), peripheral vascular, musculo-skeletal (conventional, superficial), and urology.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Diagnostic Ultrasound Indications For Use

System: Viamo c100 TUS-VC100 Diagnostic Ultrasound System

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

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	3
	Abdominal	N	N	N		N	N	N	4,5
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	
	Small Organ[1] (Specify)	N	N	N		N	N	N	2,4,5
	Neonatal Cephalic	N	N	N	N	N	N	N	4,5,6
	Adult Cephalic	N	N	N	N	N	N	N	4,5,6
	Trans-rectal	N	N	N		N	N	N	5
	Trans-vaginal	N	N	N		N	N	N	5
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	4,5
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	4,5
	Other (Urology)	N	N	N		N	N	N	4,5
Cardiac	Cardiac Adult	N	N	N	N	N	N	N	4,5,6
	Cardiac Pediatric	N	N	N	N	N	N	N	4,5,6
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N	4,5

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note : 1. Combined modes are B+M, B+CFM ,B+PW , CW, B+Color M, B/BC,B+CFM+PW ,B+PDI or DPD+PW
2. Small Organ: thyroid, testes, breast
3. 4D
4. Includes guidance of biopsy (2D)
5. THI
6. TDI

Prescription Use ___×___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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

System: Viamo c100 TUS-VC100 Diagnostic Ultrasound System
Transducer: PVU-366ST

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

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	
	Abdominal	N	N	N		N	N	N	
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ[1] (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Other (Urology)	N	N	N		N	N	N	
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Transesophageal								
Peripheral Vessel	Peripheral vessel								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note : 1. Combined modes are B+M, B+CFM ,B+PW , B/BC,B+CFM+PW ,B+PDI or DPD+PW
2. Small Organ: thyroid, testes, breast
3. Includes guidance of biopsy (2D)
4. THI

Prescription Use ___×___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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

System: Viamo c100 TUS-VC100 Diagnostic Ultrasound System
Transducer: PLU-704ST

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

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	3,4
	Small Organ[1] (Specify)	N	N	N		N	N	N	2,3.4
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	3,4
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	3,4
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Transesophageal								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N	3,4

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note : 1. Combined modes are B+M, B+CFM ,B+PW , B/BC,B+CFM+PW ,B+PDI or DPD+PW
2. Small Organ: thyroid, testes, breast
3. Includes guidance of biopsy (2D)
4. THI

Prescription Use ___×___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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

System: Viamo c100 TUS-VC100 Diagnostic Ultrasound System
Transducer: PLU-1204ST

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

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	3,4
	Small Organ[1] (Specify)	N	N	N		N	N	N	2,3,4
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	3,4
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	3,4
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Transesophageal								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N	3,4

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note : 1. Combined modes are B+M, B+CFM ,B+PW , B/BC,B+CFM+PW ,B+PDI or DPD+PW
2. Small Organ: thyroid, testes, breast
3. Includes guidance of biopsy (2D)
4. THI

Prescription Use ___×___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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

System: Viamo c100 TUS-VC100 Diagnostic Ultrasound System
Transducer: PLU-805ST

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

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	3,4
	Small Organ[1] (Specify)	N	N	N		N	N	N	2,3,4
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	3,4
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	3,4
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Transesophageal								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N	3,4

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note : 1. Combined modes are B+M, B+CFM ,B+PW , B/BC,B+CFM+PW ,B+PDI or DPD+PW
2. Small Organ: thyroid, testes, breast
3. Includes guidance of biopsy (2D)
4. THI

Prescription Use ___×___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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

System: Viamo c100 TUS-VC100 Diagnostic Ultrasound System
Transducer: PLU-1003ST

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

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ[1] (Specify)	N	N	N		N	N	N	2,3,4
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	3,4
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	3,4
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Transesophageal								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N	3,4

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note : 1. Combined modes are B+M, B+CFM ,B+PW , B/BC,B+CFM+PW ,B+PDI or DPD+PW
2. Small Organ: thyroid, testes, breast
3. Includes guidance of biopsy (2D)
4. THI

Prescription Use ___×___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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

System: Viamo c100 TUS-VC100 Diagnostic Ultrasound System
Transducer: PLU-704RST

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

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ[1] (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	N	3
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Other (Urology)	N	N	N		N	N	N	2,3
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Transesophageal								
Peripheral Vessel	Peripheral vessel								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note : 1. Combined modes are B+M, B+CFM ,B+PW , B/BC,B+CFM+PW ,B+PDI or DPD+PW
2. Includes guidance of biopsy (2D)
3. THI

Prescription Use ___×___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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

System: Viamo c100 TUS-VC100 Diagnostic Ultrasound System
Transducer: PVU-621VST

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

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ[1] (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal	N	N	N		N	N	N	3
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Other (Urology)	N	N	N		N	N	N	2,3
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Transesophageal								
Peripheral Vessel	Peripheral vessel								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note : 1. Combined modes are B+M, B+CFM ,B+PW , B/BC,B+CFM+PW ,B+PDI or DPD+PW
2. Includes guidance of biopsy (2D)
3. THI

Prescription Use ___×___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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

System: Viamo c100 TUS-VC100 Diagnostic Ultrasound System
Transducer: PVU-781VST

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

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ[1] (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal	N	N	N		N	N	N	3
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Other (Urology)	N	N	N		N	N	N	2,3
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Transesophageal								
Peripheral Vessel	Peripheral vessel								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note : 1. Combined modes are B+M, B+CFM ,B+PW , B/BC,B+CFM+PW ,B+PDI or DPD+PW
2. Includes guidance of biopsy (2D)
3. THI

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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

System: Viamo c100 TUS-VC100 Diagnostic Ultrasound System
Transducer: PSU-30ST

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

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ[1] (Specify)								
	Neonatal Cephalic								
	Adult Cephalic	N	N	N	N	N	N	N	2,3,4
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Other (Urology)								
Cardiac	Cardiac Adult	N	N	N	N	N	N	N	2,3,4
	Cardiac Pediatric								
	Transesophageal								
Peripheral Vessel	Peripheral vessel								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note : 1. Combined modes are B+M, B+CFM ,B+PW , CW, B+Color M, B/BC,B+CFM+PW ,B+PDI or DPD+PW
2. Includes guidance of biopsy (2D)
3. THI
4. TDI

Prescription Use ___×___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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

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

System: Viamo c100 TUS-VC100 Diagnostic Ultrasound System
Transducer: PSU-60ST

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

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ[1] (Specify)								
	Neonatal Cephalic	N	N	N	N	N	N	N	2,3,4
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	N	N	N	N	N	N	N	2,3,4
	Transesophageal								
Peripheral Vessel	Peripheral vessel								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note : 1. Combined modes are B+M, B+CFM ,B+PW , CW, B+Color M, B/BC,B+CFM+PW ,B+PDI or DPD+PW
2. Includes guidance of biopsy (2D)
3. THI
4. TDI

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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

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

System: Viamo c100 TUS-VC100 Diagnostic Ultrasound System
Transducer: PVU-682ST

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

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N		N	N	N	2,3
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ[1] (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Other (Urology)	N	N	N		N	N	N	2,3
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Transesophageal								
Peripheral Vessel	Peripheral vessel								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note : 1. Combined modes are B+M, B+CFM ,B+PW, B/BC,B+CFM+PW ,B+PDI or DPD+PW
2. Includes guidance of biopsy (2D)
3. THI

Prescription Use ___×___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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

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

System: Viamo c100 TUS-VC100 Diagnostic Ultrasound System
Transducer: PC-20ST

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

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ[1] (Specify)								
	Neonatal Cephalic								
	Adult Cephalic				N				
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Other (Urology)								
Cardiac	Cardiac Adult				N				
	Cardiac Pediatric				N				
	Transesophageal								
Peripheral Vessel	Peripheral vessel				N				

N = new indication; P = previously cleared by FDA; E = added under this appendix

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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

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

System: Viamo c100 TUS-VC100 Diagnostic Ultrasound System
Transducer: PVU-574MST

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

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	2
	Abdominal	N	N	N		N	N	N	3,4
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ[1] (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Other (Urology)	N	N	N		N	N	N	3,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Transesophageal								
Peripheral Vessel	Peripheral vessel								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note : 1. Combined modes are B+M, B+CFM ,B+PW, B/BC,B+CFM+PW ,B+PDI or DPD+PW
2. 4D
3. Includes guidance of biopsy (2D)
4. THI

Prescription Use ___×___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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

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

510(k) SUMMARY

1. **SUBMITTER'S NAME:**
   Toshiba Medical Systems Corporation
   1385 Shimoishigami
   Otawara-shi, Tochigi-ken, Japan 324-8550

2. **OFFICIAL CORRESPONDENT**
   Naofumi Watanabe

3. **ESTABLISHMENT REGISTRATION:**
   9614698

4. **CONTACT PERSON:**
   Orlando Tadeo, Jr.
   Manager, Regulatory Affairs
   Toshiba America Medical Systems, Inc
   2441 Michelle Drive
   Tustin, CA 92780
   (714) 669-7459

5. **Date Prepared:**
   December 27, 2017

6. **TRADE NAME(S):**
   Viamo c100 TUS-VC100 Diagnostic Ultrasound System

7. **COMMON NAME:**
   System, Diagnostic Ultrasound

8. **DEVICE CLASSIFICATION:**
   Class II
   Ultrasonic Pulsed Doppler Imaging System – Product Code: 90-IYN [per 21 CFR 892.1550]
   Ultrasonic Pulsed Echo Imaging System – Product Code: 90-IYO [per 21 CFR 892.1560]
   Diagnostic Ultrasonic Transducer – Product Code: 90-ITX [per 21 CFR 892.1570]

9. PREDICATE DEVICE:

Product	Marketed by	510(k) Number	Clearance Date
SonoBook Series Diagnostic Ultrasound System	CHISON Medical Technologies Co., Ltd.	K170374	June 6, 2017

10. REASON FOR SUBMISSION:

New device

11. DEVICE DESCRIPTION:

The Viamo c100 TUS-VC100 Diagnostic Ultrasound System is an integrated, preprogrammed, color Doppler ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications.

This system is a Track 3 device that employs a wide array of probes that include linear array, convex array and phased array. This system consists of a mobile console with keyboard control panel, power supply module, color LCD monitor and optional probes.

This system utilizes the ultrasound echo characteristics, transmits ultrasonic energy into patient body, sweeps in a certain direction, processes the signals according to the delay time and the echo strength, and images the organs by using the electronic circuits and backend controller to process, then analyzes the distance and the status of organs; and at the same time, this system utilizes Doppler and autocorrelation technology to image the blood flow and add the color-coding information to the grayscale image of B mode, then displays the image in real time.

The probes provided with this system are electrical-acoustical and acoustical-electrical transducers. The probes firstly convert the electric excitation signal to the acoustic signal and transmit the signal into the patient body, then converts the echo signals from the patient body to electric signal. The echo signal is processed and converted by DSC to image signal to output to the LCD display.

This system is a mobile, general purpose, software controlled, color diagnostic ultrasound system. Its basic function is to acquire ultrasound echo data and to display the image B-Mode (including Tissue Harmonic Imaging), M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Power Doppler Mode, Directional Power Doppler Mode, TDI Mode or a combination of these modes and 3D/4D.

12. INDICATIONS FOR USE:

The Diagnostic Ultrasound System Viamo c100 Model TUS-VC100 is indicated for the visualization of structures, and dynamic processes with the human body using ultrasound and to provide image information for diagnosis in the following clinical applications: fetal, abdominal, pediatric, small organs (breast, thyroid, testes), transvaginal, trans-rectal, neonatal cephalic, adult cephalic, cardiac (adult, pediatric), peripheral vascular, musculo-skeletal (conventional, superficial), and urology.

13. SUBSTANTIAL EQUIVALENCE:

The subject device is substantially equivalent to the SonoBook Series Diagnostic Ultrasound System, K170374, marketed by CHISON Medical Technologies Co., Ltd. The Viamo c100 `TUS-VC100 Diagnostic Ultrasound System functions in a manner similar to and is intended for the same use as the predicate device. The Viamo c100 TUS-VC100 Diagnostic Ultrasound System is similar to the predicate device in all aspects except it does not include transesophageal clinical applications, Elastography, B+PW/CW or B+CFM+PW/CW display modes.

Product Name **K number**	**SonoBook Series** **Diagnostic Ultrasound System** **K170374**	**Viamo c100 TUS-VC100** **Diagnostic Ultrasound System** **This submission**	**Comments**
Clinical Applications	Fetal, Abdominal, Pediatric, Small Organ (breast, thyroid, testes) Neonatal Cephalic, Adult Cephalic, Cardiac (adult, pediatric), Musculo-skeletal (Conventional, Superficial) Peripheral Vascular, Transesophageal, Trans-rectal, Trans-vaginal, Urology	Fetal, Abdominal, Pediatric, Small Organ (breast, thyroid, testes) Neonatal Cephalic, Adult Cephalic, Cardiac (adult, pediatric), Musculo-skeletal (Conventional, Superficial) Peripheral Vascular, Trans-rectal, Trans-vaginal, Urology	Subject device does not include Transesophageal clinical application
Operation Mode	B, FHI,B/M, M, Color M, Free Steering M ,CFM, PW,PDI,DPD,CW, 3D/4D , Elastography, TDI, Curved Panoramic ,Trapezoidal image, Compound Imaging	B, THI,B/M, M, Color M, Free Steering M CFM, PW,PDI,DPD,CW, 3D/4D , TDI, Curved Panoramic ,Trapezoidal image, Compound Imaging	Subject device does not have Elastography operation mode
Display Modes	B, 2B,4B, B/M ,M,TDI, 3D/4D,CW B/BC,B/M, B+Color M, B+PW/CW, B+CFM, B+PDI/DPD, B+CFM+PW/CW, B+ PDI/DPD+PW	B, 2B,4B, B/M ,M,TDI, 3D/4D,CW B/BC,B/M, B+Color M, B+PW, B+CFM, B+PDI/DPD, B+CFM+PW, B+ PDI/DPD+PW	Subject device does not include B+PW/CW, B+CFM+PW/CW display modes
Display Monitor	15”high-resolution color LCD monitor	15” high-resolution color LCD monitor	Same
Measurements	**2D mode:** Depth, Distance, Area: Ellipse, Trace, Spline, Trace Length, Volume: Distance, Ellipse, Ellipse + Distance, Distance Ratio, Area Ratio, IMT, Volume Flow, **M mode:** Distance, Time, Heart Rate, Velocity; **Doppler mode:** D Velocity, Time, Heart Rate, Acceleration, D Trace, S/D, Volume Flow;	**2D mode:** Depth, Distance, Area: Ellipse, Trace, Spline, Trace Length, Volume: Distance, Ellipse, Ellipse + Distance, Distance Ratio, Area Ratio, IMT, Volume Flow, **M mode:** Distance, Time, Heart Rate, Velocity; **Doppler mode:** D Velocity, Time, Heart Rate, Acceleration, D Trace, S/D, Volume Flow;	Same
Transducer Types & Connectors	Convex Array, Phased Array, Linear Array, Volume probe 1ports	Convex Array, Phased Array, Linear Array, Volume probe 1ports	Same
Acoustic Output	Derated ISPTA: 720mW/cm^2 maximum. TIS/TIB/TIC: 6.0 maximum, MI: 1.9 maximum, Derated ISPPA: 190 W/cm^{2}maximum	Derated ISPTA: 720mW/cm^2 maximum. TIS/TIB/TIC: 6.0 maximum, MI: 1.9 maximum, Derated ISPPA: 190 W/cm^{2}maximum	Same

14. SAFETY:

The device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820 and ISO 13485 Standards. This device is in conformance with the applicable parts of the IEC60601-1 (2005), IEC60601-1-2 (2007), IEC 60601-2-37 (2007), NEMA UD 2, NEMA UD3, and ISO 10993-1 standards.

15. TESTING

Non-Clinical Tests

The Viamo c100 TUS-VC100 Diagnostic Ultrasound System has been evaluated for electrical, mechanical, thermal and electromagnetic compatibility safety, biocompatibility and acoustic output. The device has been found to conform to applicable medical device safety standards in regards to thermal, mechanical and electrical safety as well as biocompatibility.

lEC 60601-1: 2005 Medical Electrical Equipment - Part 1: General Requirements for Safety

lEC 60601-1-2: 2007 Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests.

lEC 60601-2-37: 2007 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.

NEMA UD 2-2004, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Version 3.

NEMA UD3: 2004 Standards for Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment

ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

Clinical Tests

No clinical testing was required.

Software Documentation for a Moderate Level of Concern, per the FDA guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document" issued on May 11, 2005, is also included as part of this submission.

16. CONCLUSION

The Viamo c100 TUS-VC100 Diagnostic Ultrasound System is substantially equivalent to the predicate device. The subject device functions in a manner similar to and is intended for the same use as the predicate device, as described in the labeling. Based upon the bench testing, successful completion of software validation, application of risk management and design controls, it is concluded that this device is safe and effective for its intended use.