Telemed
℅ Yury Sokolov
QA/RA Manager
Highway Business Centre Savanoriu pr. 178A
Vilnius, LT-03154
LITHUANIA

February 11, 2022

Re: K211248
Trade/Device Name: ArtUs
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: December 30, 2021
Received: January 10, 2022

Dear Yury Sokolov:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211248

Device Name
ArtUs

Indications for Use *(Describe)*
ArtUs is a general purpose diagnostic ultrasound imaging system intended for use by qualified and appropriately trained healthcare professionals to conduct ultrasound scan process or fluid flow analysis of the human body.

It is intended to be used for applications in Fetal, Abdominal, Pediatric, Small Organ (breast, thyroid, testicles), Musculo-Skeletal Conventional and Superficial, Cardiac (adult and pediatric), Adult Cephalic, and Peripheral Vascular.

Modes of operation include B, M, Pulse Wave Doppler (PWD), Color Doppler (CFM), Power Doppler (PDI), Directional Power Doppler (DPDI), Combined modes (B+B, B+M, 4B, B+PWD (Duplex), B+CFM/PDI/DPDI+PWD (Triplex)), Tissue Harmonic Imaging (THI) and Inverted Tissue Harmonic Imaging (ITHI).

The clinical environments where the system can be used include physician offices, clinics, hospitals, and clinical point-of-care for diagnosis of patients.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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"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."

In accordance with 21 CFR 807.92 the following summary of information is provided:

K211248 -510k Summary

1. Identifying information

Manufacturer	TELEMED
Device Trade Name	**ArtUs**
Address	Highway Business Centre Savanoriu pr. 178A Vilnius, LT-03154, Lithuania
Telephone	+370-5 2106272 +370-5 2106273
Fax	+370-5 2306733
Web	http://www.pcultrasound.com/ www.telemed.lt
E-mail	info@telemed.lt
Contact Person	Yury Sokolov / QA Manager PRRC yury@pcultrasound.com
Date 510(k) Summary Prepared	December 30, 2021

2. Class and Predicate Information

Classification Name	Regulation Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	IYO
Diagnostic Ultrasonic Transducer	892.1570	ITX

Common Name	Diagnostic Ultrasound System		
Propietary Name	ArtUs		
Classification	Regulatory Class II		
Predicate Device	TELEMED	SmartUs	K163121
	SAMSUNG MEDISON	SONOACE R7	K112646

3. LIST OF CONSENSUS STANDARDS

The proposed device ArtUs is in conformity with the requirements of the following consensus standards:

[Rec. # 19-4] ANSI/AAMI ES60601-1 Medical electrical equipment –Part 1: General requirements for safety and essential performance,
[Rec. # 19-8] IEC 60601-1-2 Medical electrical equipment –Part 1-2 General requirements for safety and essential performance –Collateral standard: Electromagnetic compatibility – Requirements and tests
[Rec. # 12-293] IEC 60601-2-37 Medical electrical equipment –Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
[Rec. # 13-79] IEC 62304 Medical device software - Software life cycle processes
[Rec. # 5-114] IEC 62366-1 Medical devices - Part 1: Application of usability engineering to medical devices
[Rec. # 5-125] ISO 14971 Medical devices - Application of risk management to medical devices
[Rec. # 5-117] ISO 15223-1 Medical devices - Symbols to be used with medical device labels labelling and information to be supplied - Part 1: General requirements
[Rec. # 2-220] ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
[Rec. # 2-245] ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

[Rec. # 12-293] ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

4. Indication for Use

ArtUs is a general purpose diagnostic ultrasound imaging system intended for use by qualified and appropriately trained healthcare professionals to conduct ultrasound scan process or fluid flow analysis of the human body.

It is intended to be used for applications in Fetal, Abdominal, Pediatric, Small Organ (breast, thyroid, testicles), Musculo-Skeletal Conventional and Superficial, Cardiac (adult and pediatric), Adult Cephalic, and Peripheral Vascular.

Modes of operation include B, M, Pulse Wave Doppler (PWD), Color Doppler (CFM), Power Doppler (PDI), Directional Power Doppler (DPDI), Combined modes (B+B, B+M, 4B, B+PWD (Duplex), B+CFM/PDI/DPDI+PWD (Triplex)), Tissue Harmonic Imaging (THI) and Inverted Tissue Harmonic Imaging (ITHI)

The clinical environments where the system can be used include physician offices, clinics, hospitals, and clinical point-of-care for diagnosis of patients.

5. Device Description

ArtUs system is intended for the multipurpose ultrasound examinations, based on electronic linear and convex scanning.

ArtUs system is a combination of proprietary hardware and software that has been designed for real-time imaging and is intended to be a basic diagnostic tool. Its basic function is to acquire ultrasound echo data and to display the image in ultrasound B-Mode, M-Mode or combined modes. The system is designed for imaging with transducer ranges of 2 to 15 MHz.

The devices referenced in this submission represent a transportable, software-controlled, diagnostic ultrasound system with accessories. This submission does not include technology or control feature changes nor deviations from indications for use different from those demonstrated in previously cleared devices operating in ultrasound B-Mode, M-Mode or combined modes, inclusive of the predicate devices so claimed.

The ArtUs only contains the hardware and firmware, everything else (e.g. ultrasound software, database) is located on a standard PC that is connected to the ArtUs via USB 3.0. Minimum requirements are given for the PC.

The Echo Wave II software was especially designed for the TELEMED devices. Software able to reside in a Windows-based PC.

The device variant is:

- ArtUs EXT-1H ultrasound system utilizing as hardware and firmware an ultrasound engine contained in a small standalone enclosure for connection to a host PC via a USB port with external power supply;

The ArtUs can be used together with the appropriate transducers for the entire ultrasound diagnostic (2MHz to 15MHz probes).

- Transducer **L15-7H40-A5**, linear array, at a central frequency of approx. 12 MHz
- Transducer **C5-2H60-A5**, convex array at a central frequency of approx. 3.5 MHz;
- Transducer **P5-1S15-A6**, phased array at a central ultrasonic frequency of approx. 4 MHz

6. General Safety and Effectiveness.

The ArtUs ultrasound system and its accessories are designed for compliance to all applicable medical devices safety standards, as referenced in Declaration of Conformity. Prior release for manufacturing, all such devices, so designed, are tested and determined to be in full compliance with acoustic output, biocompatibility, cleaning and disinfection effectiveness.

- No additional clinical testing is required, as the indications for use are not a novel indication as shown by the predicate devices.
- Maximum acoustic output level is under by the FDA recommended limit and power level is displayed all the time.
- The system's acoustic output is in accordance with ALARA principle (As Low As Reasonably Achievable)

7. Patient Contact Materials

The parts / materials of the transducer, coming in contact with patient are:

- Acoustic Lens, Transducer Housing / Silicone Elastomer, Plastic

Standards for the biological evaluation:

- ISO-10993-1:2009, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process
- ISO-10993-5:2009, Biological Evaluation of Medical Devices Part 5: Tests for in vitro cytotoxicity
- ISO-10993-10:2010, Biological Evaluation of Medical Devices Part 10: Tests for irritation and skin sensitization

8. Software

The ArtUs system contains the hardware and software which collect and pro-processes 'rough" data and send it via USB 3.0 connection to a Windows® based PC.
The main application software is Echo Wave II software running on the PC, it is receiving data, processing and showing image/data on the screen. The main user interface shows an ultrasound image, controls and drop-out menus. The ultrasound images and calculated/measured data can be stored in memory.

9. Determination of Substantial Equivalence

The ArtUs color Doppler ultrasound system is similar to currently distributed ultrasonic pulsed echo imaging systems SmartUs (TELEMED) and SONOACE R7 (SAMSUNG MEDISON) in terms of both the intended use and technological characteristics. The ArtUs (subject device) uses the same

fundamental scientific technology as the predicate devices. All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body.

This device ArtUS is a successor of an existing licensed device SmartUs (cleared via K163121) using technologies that exist on the market as of the date of this submission.

In cosmetic design, the subject device (ArtUs) has a smaller and lighter structure and appearance than SmartUs due to modern electronic components.

The PCBs in the system are minimized in their size and layout, while the overall circuit operation principle is not changed.

The connection of new ultrasound transducers is easier and more reliable using the new generation of connectors.

The connection to the PC by USB 3.0 (comparing USB 2.0 connection for SmartUs) is increasing the dataflow performance between the device and PC.

The subject device ArtUs meets FDA requirements for Track 3 devices, have biosafety equivalence, and conform to applicable electromedical devices safety standards. All the safety and performance tests of the device meet the essential requirements.

Therefore, the system has the same classification and is substantially equivalent to predicate devices.

Any differences between the predicate and the new device have no impact on safety or efficacy of the new device and do not raise any new potential or increased safety risks, and the new device is equivalent in performance to existing legally marketed devices.

10. Conclusion

In accordance with the FDA and based on the information provided in this Premarket notification, TELEMED considers the ArtUs to be as safe as effective and performance is substantially equivalent to the predicate devices described herein.