DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

November 3, 2016

TELEMED
% Mr. Yury Sokolov
Engineering Manager
Dariaus ir Gireno str. 42
Vilnius, LT-02189
LITHUANIA

Re: K161968
Trade/Device Name: MicrUs
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX
Dated: October 20, 2016
Received: October 24, 2016

Dear Mr. 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. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*

K161968

Device Name
MicrUs

Indications for Use *(Describe)*

MicrUs ultrasound imaging system is intended to be used for applications in fetal, abdominal, pediatric, small organ (breast, thyroid, testicles), neonatal cephalic, adult cephalic, musculo-skeletal (conventional), musculo-skeletal (superficial), cardiac adult, peripheral vessel (B and M-mode imaging, including imaging for needle guidance). It is possible to provide diagnostic information outside of an imaging lab, including at the bedside systems, for navigated medical application, in operating rooms/critical care units.

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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1.3 Indications for Use

All indications for use of subject devices and probes are identified in the table forms:

System MicrUs EXT-1H		Fetal*, Abdominal*, Pediatric*, Small Organ* (Breast, Thyroid, Testicles), Neonatal Cephalic*, Adult Cephalic*, Musculo-skeletal* (Conventional), Musculo-skeletal* (Superficial), Cardiac Adult*, Peripheral vessel*	Table 1.3-1
Transducers	**L12-5L40S-3**	Pediatric*, Small Organ* (Breast, Thyroid, Testicles), Neonatal Cephalic*, Adult Cephalic*, Musculo-skeletal* (Conventional), Musculo-skeletal* (Superficial), Peripheral vessel*	Table 1.3-2
	L15-6L25S-3	Pediatric*, Small Organ* (Breast, Thyroid, Testicles), Neonatal Cephalic*, Adult Cephalic*, Musculo-skeletal* (Conventional), Musculo-skeletal* (Superficial), Peripheral vessel*	Table 1.3-3
	C5-2R60S-3	Fetal*, Abdominal*, Pediatric *	Table 1.3-4
	MC8-4R20S-3	Small Organ* (Breast, Thyroid, Testicles), Cardiac Adult*, Peripheral vessel*	Table 1.3-5

*Including Imaging for needle guidance

Diagnostic Ultrasound Indications for Use Form

System: **MicrUs EXT-1H**

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

Table 1.3-1

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other* (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[2]	**N**	**N**				**N B+M**	
	Abdominal[2]	**N**	**N**				**N B+M**	
	Intraoperative (specify)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric[2]	**N**	**N**				**N B+M**	
	Small Organ (specify)[2]	**N**[1]	**N**[1]				**N B+M**	
	Neonatal Cephalic	**N**	**N**				**N B+M**	
	Adult Cephalic	**N**	**N**				**N B+M**	
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (Non-Card)							
	Musculo-skeletal (**Conventional**) [2]	**N**	**N**				**N B+M**	
	Musculo-skeletal (**Superficial**) [2]	**N**	**N**				**N B+M**	
	Intravascular							
	Other (specify)							
Cardiac	Cardiac Adult	**N**	**N**				**N B+M**	
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral vessel[2]	**N**	**N**				**N B+M**	
	Other (specify)							

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

Note [1] - Small Organs (specifically Breast, Thyroid, Testicles)

Note [2] - Includes Imaging for Needle Guidance

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form

System: **MicrUs EXT-1H** **Transducer:** Linear array **L12-5L40S-3**

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

Table 1.3-2

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other* (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[2]							
	Abdominal[2]							
	Intraoperative (specify)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric[2]	**N**	**N**				**N B+M**	
	Small Organ (specify)[2]	**N**[1]	**N**[1]				**N B+M**	
	Neonatal Cephalic	**N**	**N**				**N B+M**	
	Adult Cephalic	**N**	**N**				**N B+M**	
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (Non-Card)							
	Musculo-skeletal (**Conventional**) [2]	**N**	**N**				**N B+M**	
	Musculo-skeletal (**Superficial**) [2]	**N**	**N**				**N B+M**	
	Intravascular							
	Other (specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral vessel[2]	**N**	**N**				**N B+M**	
	Other (specify)							

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

Note [1] - Small Organs (specifically Breast, Thyroid, Testicles)

Note [2] - Includes Imaging for Needle Guidance

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form

System: **MicrUs EXT-1H** **Transducer:** Linear array **L15-6L25S-3**

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

Table 1.3-3

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other* (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[2]							
	Abdominal[2]							
	Intraoperative (specify)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric[2]	**N**	**N**				**N B+M**	
	Small Organ (specify)[2]	**N**[1]	**N**[1]				**N B+M**	
	Neonatal Cephalic	**N**	**N**				**N B+M**	
	Adult Cephalic	**N**	**N**				**N B+M**	
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (Non-Card)							
	Musculo-skeletal (**Conventional**) [2]	**N**	**N**				**N B+M**	
	Musculo-skeletal (**Superficial**) [2]	**N**	**N**				**N B+M**	
	Intravascular							
	Other (specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral vessel[2]	**N**	**N**				**N B+M**	
	Other (specify)							

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

Note [1] - Small Organs (specifically Breast, Thyroid, Testicles)

Note [2] - Includes Imaging for Needle Guidance

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form

System: **MicrUs EXT-1H** **Transducer:** Convex array **C5-2R60S-3**

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

Table 1.3-4

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other* (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[2]	**N**	**N**				**N B+M**	
	Abdominal[2]	**N**	**N**				**N B+M**	
	Intraoperative (specify)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric[2]	**N**	**N**				**N B+M**	
	Small Organ (specify)[2]							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (Non-Card)							
	Musculo-skeletal (**Conventional**) [2]							
	Musculo-skeletal (**Superficial**) [2]							
	Intravascular							
	Other (specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral vessel[2]							
	Other (specify)							

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

Note [1] - Small Organs (specifically Breast, Thyroid, Testicles)

Note [2] - Includes Imaging for Needle Guidance

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form

System: **MicrUs EXT-1H** **Transducer:** Convex array **MC8-4R20S-3**

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

Table 1.3-5

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other* (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[2]							
	Abdominal[2]							
	Intraoperative (specify)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric[2]							
	Small Organ (specify)[2]	**N**[1]	**N**[1]				**N B+M**	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (Non-Card)							
	Musculo-skeletal (**Conventional**) [2]							
	Musculo-skeletal (**Superficial**) [2]							
	Intravascular							
	Other (specify)							
Cardiac	Cardiac Adult	**N**	**N**				**N B+M**	
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral vessel[2]	**N**	**N**				**N B+M**	
	Other (specify)							

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

Note [1] - Small Organs (specifically Breast, Thyroid, Testicles)

Note [2] - Includes Imaging for Needle Guidance

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510k Summary

1. Identifying information

Manufacturer	TELEMED
Address	Dariaus ir Gireno str. 42 Vilnius LT-02189 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 yury@telemed.lt
Contact	Yury Sokolov / Engineering Manager
Name of Device	**MicrUs**

2. Class and Predicate Information

Classification Name	FR Number	Product Code
Ultrasonic Pulsed Echo Imaging System	892.1560	IYO
Diagnostic Ultrasonic Transducer	892.1570	ITX

Common Name	Ultrasound imaging system
Propietary Name	MicrUs
Class	Regulatory Class II
Predicate Device	TELEMED; Echo Blaster K102253

3. Performance Standards

The MicrUs has been designed to meet the following:
Safety and EMC Requirements for Medical Equipment:

IEC 60601-1: 2005, Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-2: 2007, Part 1: General requirements for basic safety and essential performance, 2.Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-2-37:2007 Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
ISO-10993-1:2009, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing within a risk management process.
ISO-10993-5, Biological Evaluation of Medical Devices Part 5: Tests for in vitro cytotoxicity, 1999
ISO-10993-10:2010, Biological Evaluation of Medical Devices, Part 10: Tests for irritation and skin sensitization
IEC 62304: 2006 Medical device software -- Software life cycle processes
NEMA UD 2-2004: 2003, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
NEMA UD 3-2004: 2004, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
AIUM MUS: 2002, Medical Ultrasound Safety

Essential Requirements of Council Directive 93/42/EEC (Medical Device Directive)

The system's acoustic output is in accordance with ALARA principle (as low as reasonably achievable)

4. Indication for Use

MicrUs ultrasound imaging system is intended to be used for applications in fetal, abdominal, pediatric, small organ (breast, thyroid, testicles), neonatal cephalic, adult cephalic, musculo-skeletal (conventional), musculo-skeletal (superficial), cardiac adult, peripheral vessel (B and M-mode imaging, including imaging for needle guidance). It is possible to provide diagnostic information outside of an imaging lab, including at the bedside systems, for navigated medical application, in operating rooms/critical care units.

5. Device Description

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

MicrUs 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. The system is based on a modular and flexible architecture allowing for both mobile and stationary (installed) configurations. 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 or M-Mode, inclusive of the predicate devices so claimed.

The **MicrUs** only contains the hardware and firmware, everything else (e.g. ultrasound software, database) is located on a standard PC that is connected to the **MicrUs** via USB 2.0/3.0. Minimum requirements are given for the PC. All echo-images (sonograms) are saved on the PC and can there be evaluated, printed and archived.

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

The basic modification **MicrUs EXT-1H** ultrasound system utilizing as hardware and firmware an ultrasound engine contained in a small stand alone enclosure for connection to a host PC via a USB port.

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

- probe, linear array transducer, at a central ultrasonic frequency of approx. 7.5 MHz, model **L12-5L40S-3**;
- probe, linear array at a central ultrasonic frequency of approximately 10 MHz,

model **L15-6L25S-3**;

- probe, convex array at a central ultrasonic frequency of approximately 3.5 MHz, model **C5-2R60S-3**;
- probe, convex array at a central ultrasonic frequency of approximately 6.5 MHz, model **MC8-4R20S-3**.

6. General Safety and Effectiveness

The **MicrUs** ultrasound system is similar to currently distributed ultrasonic pulsed echo imaging systems.

There are no technological characteristics or features or indications for use in this Submission that are not previously evaluated and approved in the predicate devices, nor are there such technologies, features and indications for use not commonly used in the practice of diagnostic ultrasound.

The **MicrUs** ultrasound system and its accessories are designed for compliance to all applicable medical devices safety standards, as referenced in DECLARATION OF CONFORMITY (Appendix 05). 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 in Section **1.5 Predicate Device Comparison**.

Maximum acoustic output level is under by the FDA recommended limit and power level is displayed all the time.

7. Patient Contact Materials

The materials of probes, coming in contact with patient are:

- RTV Silicone
- ABS+PC (Acrylonitrile Butadiene Styrene + polycarbonate)

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 **MicrUs** system contains the hardware and software which collect and pro-processes 'rough" data and send it via USB 2.0/3.0 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. Conclusion

In accordance with the FDA and based on the information provided in this Premarket notification, TELEMED concludes that the **MicrUs** is safe and effective and substantially equivalent to predicate devices described herein.