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

Biim Ultrasound AS
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street, NW
BUFFALO MN 55313

October 27, 2017

Re: K173138
Trade/Device Name: Biim™ Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX, LLZ
Dated: September 27, 2017
Received: September 29, 2017

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

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

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

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

Sincerely,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173138

Device Name
Biim™ Diagnostic Ultrasound System

Indications for Use *(Describe)*
The Biim™ Diagnostic Ultrasound System is intended for diagnostic ultrasound imaging of the human body. Specific clinical applications include:

- Musculo-skeletal (conventional and superficial)
- Needle guidance
- Pediatric
- Peripheral Vessel
- Small Organ (breast, thyroid, parathyroid, testicles)

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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"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."

Table 1 - Indications for Use Form – Biim Diagnostic Ultrasound System

System:	Biim™ Diagnostic Ultrasound System
Transducer:	Currently Supported (Note 1)
Intended Use:	Diagnostic ultrasound imaging of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	**Specific (Tracks I & III)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler (CD)**	**Combined (B+CD)**	**Other* (Color Power Doppler)**
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal							
	Intra-operative (Abdominal organs and vascular)							
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic							
& Other	Pediatric	N						
	Small Organ (breast, thyroid, testicles)	N						
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	N						
	Musculo-skel. (Superfic.)	N						
	Intravascular							
	Other: (Gynecology)							
	Other							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Intra-cardiac							
	Other (spec.)							
Peripheral	Peripheral vessel	N						
Vessel	Other: Needle guidance	N						

Prescription Use (Per 21 CFR 801.109)
N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

*Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

1. Supported transducer models are: Biim L12-4 Linear Array Transducer See the corresponding table.
2. Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for nerve block procedures.

Table 2 - Indications for Use Form – Biim L12-4 Linear Array Transducer

System:	Biim™ Diagnostic Ultrasound System
Transducer:	L12-4 Linear Array Transducer
Intended Use:	Diagnostic ultrasound imaging of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	**Specific (Tracks I & III)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler (CD)**	**Combined (B+CD)**	**Other* (Color Power Doppler)**
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal							
	Intra-operative (Abdominal organs and vascular)							
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic							
& Other	Pediatric	N						
	Small Organ (breast, thyroid, testicles)	N						
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	N						
	Musculo-skel. (Superfic.)	N						
	Intravascular							
	Other: (Gynecology)							
	Other:							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Intra-cardiac							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	N						
	Other: Needle guidance	N						

Prescription Use (Per 21 CFR 801.109)
N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

*Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

1. Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for nerve block procedures.

510(k) Summary of Safety and Effectiveness

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

Date Prepared:	August 11, 2017
Submitter:	Biim Ultrasound AS Frydenlundsgt 9 Narvik, Norway 8516
Contact Person:	Christopher Hartzog CHRQ Consulting, LLC
Telephone:	425.954.6312
FR Numbers/Product Codes:	892.1560/IYO, Ultrasonic Pulsed Echo Imaging System 892.1570/ITX, Diagnostic Ultrasound Transducer
Common Name:	Diagnostic Ultrasound System with Accessories
Trade Name:	Biim™ Diagnostic Ultrasound System
Regulatory Class:	Class II
Classification Panel:	Radiology
Predicate Device:	(K163138) Clarius Mobile Health Corp., Clarius Ultrasound System (Primary Predicate) (K162549) Philips Healthcare, Inc. Lumify Diagnostic Ultrasound System (Reference Device)
Intended Use/ Indications For Use:	The Biim Ultrasound System is intended for diagnostic ultrasound imaging of the human body. Specific clinical applications include: • Musculo-skeletal (conventional and superficial) • Needle guidance • Pediatric • Peripheral Vessel • Small Organ (breast, thyroid, parathyroid, testicles)

Device Description:	The Biim Diagnostic Ultrasound System is a portable, general-purpose, software-controlled sonography system based on a digital architecture used to acquire and display high-resolution, real-time ultrasound data through a commercial off-the-shelf iOS or Android device. The Biim Diagnostic Ultrasound System supports wireless transducer connectivity of the ultrasound images to the display device. The Biim Diagnostic Ultrasound System consists of: • A commercial off-the-shelf iOS or Android display device • Biim Ultrasound software running as an app on the display device • The wireless Biim linear array transducer with Biim Ultrasound firmware. • Lithium-Ion rechargeable battery • Battery charger
Comparison of the Design and Technological Characteristics	The Biim Diagnostic Ultrasound System has similar indications for use, construction, manufacturing materials, operating principals and specifications as the predicate device. The Biim Diagnostic Ultrasound System is similar to the Clarius Ultrasound System in that it is also a portable, general-purpose, software-controlled, diagnostic ultrasound system used to acquire and display high-resolution, real-time ultrasound data through a commercial off-the-shelf (COTS) iOS or Android display device. Comparable to the Clarius Ultrasound System, the Biim Diagnostic Ultrasound System employs wireless transducers employing Wi-Fi-based technology to communicate with tablet devices. This allows the user to export ultrasound images and display them upon Apple iOS or Android portable personal devices. The principle difference between the Biim Diagnostic Ultrasound System and its predicate Clarius device is that the Biim Diagnostic Ultrasound System includes DICOM 3.0 storage and echo service class user features while the Clarius device does not. The Philips Lumify device is provided as a reference device due to its comparable technology to the Biim Diagnostic Ultrasound System specifically its use of DICOM 3.0 services and an L12-4 linear array transducer. A comparison of the clinical, design and technological characteristics of the Biim Diagnostic Ultrasound System to the currently marketed, primary predicate device and reference device is provided in Table 1 and Table 2 below.

Table 1 - Predicate Comparison Chart - Clinical Uses

Clinical Uses	Submitted Device **Biim Ultrasound AS** **Biim Diagnostic Ultrasound System (this premarket notification)**	Primary Predicate Device **Clarius Mobile Health** **Clarius Ultrasound System (K163138)**	Reference Device **Philips Healthcare** **Lumify Ultrasound System (K162549)**
Intended Use	Diagnostic ultrasound imaging of the human body.	Diagnostic ultrasound imaging or fluid flow analysis of the human body.	Diagnostic ultrasound imaging or fluid flow analysis of the human body.
Indications for Use			
Pediatric applications	Yes	Yes	Yes
Small Organ (breast, thyroid, testicles) applications	Yes	Yes	Yes
Musculo-skel. (Convent.) applications	Yes	Yes	Yes
Musculo-skel. (Superfic.) applications	Yes	Yes	Yes
Peripheral vessel applications	Yes	Yes	Yes
Needle guidance applications	Yes	Yes	
Patient Group			
Gender: Both sexes allowed	Yes	Yes	Yes
Patient age: Adult, Pediatric	Yes	Yes	Yes

Table 2 - Predicate Comparison Chart - Technical Features

Technical Features	Submitted Device **Biim Ultrasound AS** **Biim Diagnostic Ultrasound System (this premarket notification)**	Primary Predicate Device **Clarius Mobile Health** **Clarius Ultrasound System (K163138)**	Reference Device **Philips Healthcare** **Lumify Ultrasound System (K162549)**
System features	Wireless Transducer iPad or Android Tablet Console	Wireless Transducer iPad or Android Tablet Console	USB Transducer Android Tablet Console
Transducer Types	L12-4 Linear Array - Wireless	L7 Linear Array - Wireless	L12-4 Linear Array - USB Cable
		C3 Curved Linear Array - Wireless	C5-2 Curved Linear Array - USB Cable
Transducer Frequency	4 - 12 MHz	4 - 13 MHz	4 - 12 MHz
Global Maximum Outputs/Worst Case Setting (non-opthalmic)	$I_{spta.3}$: ≤ 720 mW/cm2	$I_{spta.3}$: ≤ 720 mW/cm2	$I_{spta.3}$: ≤ 720 mW/cm2
	MI ≤ 1.9	*MI ≤ 1.9*	*MI ≤ 1.9*
	TI ≤ 6.0	*TI ≤ 6.0*	*TI ≤ 6.0*
Acoustic Output Display	Display Feature for Higher Outputs	Display Feature for Higher Outputs	Display Feature for Higher Outputs
	MI Output Display	MI Output Display	MI Output Display
	TI Output Display	TI Output Display	TI Output Display
Modes of Operation	B-mode Grayscale Imaging	B-mode Grayscale Imaging, color velocity and combined modes.	B-mode Grayscale Imaging, Color Doppler and combined modes.
No. Transmit Channels	8	Unknown	Unknown
No. Receive Channels	8	Unknown	Unknown
DICOM	DICOM 3.0 storage and echo service class user features.	None	DICOM 3.0 storage, print, and modality worklist service class user features.
	NEMA PS3 2016		NEMA PS3 2016
Patient Contact Materials	All patient contact materials biocompatible per ISO 10993 series	Biocompatible per K163138	Biocompatible per K152899
Product Safety Certification	IEC 60601-1	IEC 60601-1	IEC 60601-1
	IEC 60601-2-37	IEC 60601-2-37	IEC 60601-2-37
	Device with transducers: Class II/internally powered ME equipment.	Device with transducers: Class II/internally powered ME equipment.	Device with transducers: Class II/internally powered ME equipment.
	Transducers: Type BF Applied parts, IPX7	Transducers: Type BF Applied parts, IP37	Transducers: Type BF Applied parts, IP47
	Ordinary Equipment/Continuous Operation	Ordinary Equipment/Continuous Operation	Ordinary Equipment/Continuous Operation
			Non-AP/APG

Technical Features	Submitted Device **Biim Ultrasound AS** **Biim Diagnostic Ultrasound System (this premarket notification)**	Primary Predicate Device **Clarius Mobile Health** **Clarius Ultrasound System (K163138)**	Reference Device **Philips Healthcare** **Lumify Ultrasound System (K162549)**
	Non-AP/APG		
EMC Compliance	IEC 60601-1-2 FCC Part 15 ETSI EN 300 328 ETSI EN 301 489 Bluetooth 2.0 IEEE 802.11 b/g	IEC 60601-1-2 FCC Part 15 ETSI EN 300 328 ETSI EN 301 489	IEC 60601-1-2
System Characteristics	Supported Display: Apple iPad and Android Tablets	Supported Display: Apple iPad and Android Tablets	Supported Display: Android Tablets
	256 gray shades in 2D	256 gray shades in 2D	256 gray shades in 2D
	Small, handheld and battery operated probe.	Small, handheld and battery operated probe.	Small, handheld probe.
	Remotely control the ultrasound system	Remotely control the ultrasound system	
	Ultrasound Transmit, Receive and processing functions for basic 2D imaging	Ultrasound Transmit, Receive and processing functions for basic 2D imaging	Ultrasound Transmit, Receive and processing functions for 2D and color imaging
	Transmit voltage and current monitoring with hardware limits to ensure safe and proper operation.	Transmit voltage and current monitoring with hardware limits to ensure safe and proper operation.	Transmit voltage and current monitoring with hardware limits to ensure safe and proper operation.
	Power On/Off button	Power On/Off button	Power On/Off button
	User controls for depth, image save and freeze.	User controls for depth, image save and freeze.	User controls for depth, image save and freeze.
	Led indicator for On/Off/standby/error status and Tablet link status.	Led indicator for On/Off/standby/error status and Tablet link status.	
	User replaceable battery to allow for continuous use.	User replaceable battery to allow for continuous use.	Receives power from tablet via USB
	Probe wireless connectivity to tablet	Probe WiFi wireless connectivity to tablet	Probe USB cable connection to tablet
	Small handheld probe: • Height: 41 mm (1.61 in) • Width: 58 mm (2.28 in) • Length: 150 mm (5.90 in)	Small handheld probe	Small handheld probe
	Lightweight, ergonomic design	Lightweight, ergonomic design	Lightweight, ergonomic design

Technical Features	Submitted Device **Biim Ultrasound AS** **Biim Diagnostic Ultrasound System (this premarket notification)**	Primary Predicate Device **Clarius Mobile Health** **Clarius Ultrasound System (K163138)**	Reference Device **Philips Healthcare** **Lumify Ultrasound System (K162549)**
	• Weight : 210 g (7.4 oz)		
Operating Environmental Limits	5 to 90% RH non-condensing 10°C (50°F) to 30°C (86°F)	620 hPa to 1060 hPa 15 to 95% RH 0°C (32°F) to 40°C (104°F)	700 hPa to 1060 hPa 15 to 95% RH 5°C (41°F) to 40°C (104°F)
Storage Environmental Limits	5to 95% RH -20°C (-4°F) to 60°C (140°F)	0 to 95% RH -20°C (-4°F) `to 50°C (122°F)	500 hPa to 1060 hPa 0 to 95% RH -34°C (-29°F) to 70°C (158°F)
Power Supply/Battery Charger	Battery charger for detachable battery Input: 100V - 240 V Rating Frequency: 50/60Hz Output: 5VDC 1.0 A	Battery charger for replaceable battery Input: 100V - 240 V Rating Frequency: 50/60Hz Output: 12VDC 1.5 A	Receives power from tablet via USB
Battery	User replaceable Li-Ion battery pack, 3.7V	User replaceable Li-Ion battery pack, 3.7V	N/A - Probe receives power from tablet via USB cable
510(k) Track	Track 3	Track 3	Track 3

Determination of Substantial Equivalence

They Biim Diagnostic Ultrasound System is a Track 3 system that employs the same fundamental scientific technology as that cleared with the Clarius Ultrasound System (K163138). All indications for use introduced by Biim Ultrasound are indications used by the predicate device.

Summary of Non-Clinical Tests:	The Biim Diagnostic Ultrasound System has been found to conform to the system specifications, thermal, electrical, electromagnetic and mechanical safety, and to FDA consensus, medical device safety standards, and international harmonized standards. The Biim Diagnostic Ultrasound System and its applications comply with the following standards: 1. AAMI/ANSI/ES 60601-1:2005/(R)2012 And A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance 2. AAMI/ANSI/IEC 60601-1-2 Medical Electrical Equipment, Part 1: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests 3. 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

	4. IEC 62304 Medical device software - Software life cycle processes 5. AAMI/ANSI/IEC 62366-1:2015 Medical devices - Application of usability engineering to medical devices 6. AAMI/ANSI/ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing 7. AAMI/ANSI/ISO 10993-5:2014 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity 8. AAMI/ANSI/ISO 10993-10:2014 Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity 9. ISO 14971 Medical devices – application of risk management to medical devices The following quality assurance measures were applied to the development of the system: • Risk Analysis • Requirements Reviews • Design Reviews • Testing on unit level (Module verification) • Integration testing (System verification) • Final Acceptance Testing (Validation) • Performance testing (Verification) • Safety testing (Verification) • Usability validation Patient contact materials are biocompatible.
Summary of Clinical Tests	The Biim Diagnostic Ultrasound System introduces no new indications for use, modes, features, or technologies as compared to the currently marketed and predicate device that require clinical testing. The clinical safety and effectiveness of ultrasound systems with these characteristics are well accepted for both the currently marketed predicate and subject device.
Conclusions:	The Biim Diagnostic Ultrasound System has similar indications for use, construction, manufacturing materials, operating principals and specifications as the predicate device. Therefore, Biim Ultrasound AS considers the Biim Diagnostic Ultrasound System substantially equivalent to the predicate device.
514 Performance Standards:	There are no Sec. 514 performance standards for this device.
Prescription Status:	This is a prescription device. The prescription device statement appears in the labeling.
Sterilization Sites:	Not applicable. No components supplied sterile.
Track:	This is a Track 3 device.