October 19, 2018

Echolight S.p.a
% Maurizio Pantaleoni
CEO
ISEMED srl
Via P. Togliatti 19/X
IMOLA, BO 40026
ITALY

Re: K180516
Trade/Device Name: EchoS
Regulation Number: 21 CFR 892.1180
Regulation Name: Bone Sonometer
Regulatory Class: Class II
Product Code: MUA
Dated: August 31, 2018
Received: September 21, 2018

Dear Maurizio Pantaleoni:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

for
Robert A. 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)*
K180516

Device Name
EchoS

Indications for Use *(Describe)*

EchoS is a non-invasive ultrasound (US) bone sonometer. EchoS works together with EchoStudio software. EchoStudio analyzes the ultrasound signals in order to compute the diagnostic parameters (BMD_{US}, T-score, and Z-score) and to assess fracture risk through the integrated FRAX® software.

The BMD_{US} Index is a clinical measure based on ultrasound variables of the lumbar spine or femoral neck which is highly correlated with the value of BMD as provided by DXA at the same anatomical location (BMD_{DXA}), with a standard error of the estimate of 0.044 grams/cm² for lumbar spine and 0.038 grams/cm² for femoral neck measurements. BMD_{US} Index is expressed in grams/cm² and it is based on a proprietary internal database, obtained from clinical data on adult white females and males, while T- and Z-score are derived from comparison to a normative X-ray absorptiometry reference database (NHANES). BMD_{US} Index has a precision comparable to that of x-ray absorptiometry, which makes it suitable for monitoring bone changes in women.

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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510(k) Summary

This 510(k) Summary is being submitted as required by **21 CFR 807.92.**

1. General Information

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Summary Prepared Date: February 15, 2018

2. Names

- **Device Name:** EchoS
- **Common Name**: Bone sonometer
- **Regulation Number**: 21 CFR 892.1180
- **Product Code**: MUA ; class II

3. Predicate Devices

The EchoS is substantially equivalent to the following predicate devices:

Applicant	Device name	510(k) Number
CyberLogic, Inc.	Ultrascan 650	K161919 - Primary Predicate Device
Beam-Med Ltd.	Sunlight MiniOmni	K110646 - Secondary Predicate Device

4. Device Description

The subject device, EchoS, consists of two main parts: the equipment EchoS device with its own probe and the software EchoStudio.

- The EchoS device consists of EchoS device together with its probe,
- The software EchoStudio: user interface and algorithmic calculation software provided in installation disc.

The EchoS device is connected to the computer via the USB port, and it is controlled by the EchoStudio to send the transmitting parameters to the EchoS device and to acquire the ultrasound

(US) signals from EchoS device in order to calculate the BMD_{US} and the other diagnosis parameters.

The EchoS System is a PC-based device that employs an ultrasound probe to collect ultrasound (RF) signals for echographic applications. During the measurement, the ultrasound convex probe, connected by a standard connector to the EchoS device, is applied directly to the skin in correspondence of the lumbar vertebrae or proximal femur, applying a thin layer of ultrasound gel between the probe surface and the skin to facilitate acoustic coupling. The ultrasound waves emitted by the probe are reflected by the bone, and then detected by the same probe.

During the scan, the algorithm automatically detects the bone interfaces and calculates the region of interest (ROIs) for data analysis. The automatic data processing is performed through the following steps: a custom developed signal pre-processing chain performs filtering, amplification and A/D conversion operations on the RF signals that are then passed to the EchoStudio software.

EchoStudio includes RF signal analysis and spectral comparison with reference models for the calculation of diagnostic parameters (BMD_{US}, T-score, Z-score), and generation of the final medical report. The relevant scan depth, focus position, and visualization parameter settings can be adjusted and set by the interface of the software - EchoStudio.

EchoStudio software provides BMD_{US} (in g/cm^2), T-score and Z-score. It also estimates the 10-year osteoporotic fracture risk calculated with the original FRAX® algorithm that is integrated in the device.

5. Indications for Use

EchoS is a non-invasive ultrasound (US) bone sonometer. EchoS works together with EchoStudio software.

EchoStudio analyzes the ultrasound signals in order to compute the diagnostic parameters (BMD_{US}, T-score, and Z-score) and to assess fracture risk through the integrated FRAX® software.

The BMD_{US} index is a clinical measure based on ultrasound variables of the lumbar spine or femoral neck which is highly correlated with the value of BMD as provided by DXA at the same anatomical location (BMD_{DXA}), with a standard error of the estimate of 0.044 $grams/cm^2$ for lumbar spine and 0.038 $grams/cm^2$ for femoral neck measurements. BMD_{US} is expressed in $grams/cm^2$ and it is based on a proprietary internal database, obtained from clinical data on adult white females and males, while T- and Z-score are derived from comparison to a normative X-ray absorptiometry reference database (NHANES). BMD_{US} Index has a precision comparable to that of x-ray absorptiometry, which makes it suitable for monitoring bone changes in women.

6. Comparison of technological characteristics with the predicate devices

The EchoS is substantially equivalent to the following predicate devices:

Applicant	Device name	510(k) Number
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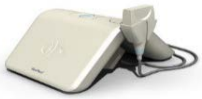
Beam-Med Ltd.	Sunlight MiniOmni	K110646 - Secondary Predicate Device

The comparison between the EchoS and the predicate devices is summarized in the following table and discussed below.

	SUBJECT DEVICE	Primary Predicate Device (PD1)	Secondary predicate device (PD2)
PRODUCT NAME	**EchoS System**	Ultrascan 650 (K161919)	Sunlight MiniOmni (K110646)
APPLICANT (MANUFACTURER)	Echolight S.p.a.	CyberLogic, Inc.	BeamMed Ltd.
FIGURE			
CLASSIFICATION:	Class II Reg. Number: 892.1180 "bone sonometer" Product Code: MUA	Class II Reg. Number: 892.1180 "bone sonometer" Product Code: MUA	Class II Reg. Number: 892.1180 "bone sonometer" Product Code: MUA

INDICATIONS FOR USE:	EchoS is a non-invasive ultrasound (US) bone sonometer. EchoS works together with EchoStudio software. EchoStudio analyzes the ultrasound signals in order to compute the diagnostic parameters (BMD_{US}, T-score, and Z-score) and to assess fracture risk through the integrated FRAX® software. The BMD_{US} Index is a clinical measure based on ultrasound variables of the lumbar spine or femoral neck which is highly correlated with the value of BMD of the same anatomical location as provided by DXA (BMD_{DXA}), with a standard error of the estimate of 0.044grams/cm^2 for lumbar spine and 0.038 grams/cm^2 for femoral neck measurements. BMD_{US} Index is expressed in grams/cm^2 and as a T- and Z-score, derived from comparison to a normative x-ray absorptiometry reference database. BMD_{US} Index has a precision comparable to that of x-ray absorptiometry, which makes it suitable for monitoring bone changes in women.	UltraScan 650 can be used to determine BMD_{US} Index in adult men and women and to assess appendicular fracture risk in postmenopausal women. The BMD_{US} Index is a clinical measure based on ultrasound variables of the forearm which is highly correlated with the value of BMD of the 1/3 radius as provided by DXA, with a standard error of the estimate of 0.041 grams/cm^2 . BMD_{US} Index is expressed in grams/cm^2 and as a T- and z-score, derived from comparison to a normative x-ray absorptiometry reference database. BMD_{US} Index has a precision comparable to that of x-ray absorptiometry, which makes it suitable for monitoring bone changes in postmenopausal women.	Sunlight MiniOmni Ultrasound Bone Sonometers is a non-invasive device. The output is also expressed as a T-score and a Z-score, and can be used in conjunction with other clinical risk factors as an aid to the physician in the diagnosis of osteoporosis and other medical conditions leading to reduced bone strength and, ultimately, in the determination of fracture risk.
PATIENT POPULATION	Women between the ages of 51 and 70 years	Assess appendicular fracture risk in postmenopausal women and for determination of BMD_{US} Index in adult men and women	Female 50-65 years old
TECHNOLOGY:			
FOUNDAMENTAL TECHNOLOGIES	Ultrasound	Ultrasound	Ultrasound
MEASUREMENT MODE	reflection	Through-transmission	Axial Transmission

MEASUREMENT LOCATION	Lumbar Spine Femoral Neck	1/3 radius	Peripheral: Distal one-third of the radius & the proximal & third phalanx & fifth metatarsal
DIAGNOSTIC PARAMETERS	BMD_{US} T-Score Z-Score Fracture risk estimation calculated with the FRAX algorithm integrated in the device	BMD_{US} T-score Z-score Fracture risk estimation	T-score Z-score (WHO compliant) SOS
CORRELATION $BMDS_{US}$ TO BMD_{DXA}	0.94 for lumbar spine 0.93 for femoral neck	0.93	Not declared
Embedded databases	• Proprietary Internal database based on clinical studies on adult white females and males • NHANES reference database	Internal reference database based on adult white females and males, NHANES reference database	reference database
PERFORMANCES:			
SAFETY & EMC	EN 60601-1 -Safety EN 60601-2-37 - -Safety IEC 60601-1-2 -EMC	IEC 60601-1 - Safety IEC 60601-1-2 – EMC	lEC 60601-2-37: 2001 lEC 60601-1: 2005 IEC 60601-1-2:2007
ACOUSTIC OUTPUT PARAMETERS	I_{SPTA3}, I_{SPPA} and MI under the limit of the "other" diagnostic ultrasound systems	Maximum acoustic output Pulse intensity integrals Pulse total energy Pulse duration Pulse repetition rate Pulse average intensity Time average intensity Acoustic signal center frequency Beam total power	I_{SPTA3}, I_{SPPA} and MI under the limit of the "other" diagnostic ultrasound systems
BIOCOMPATIBILITY	ISO 10993-1	ISO 10993-1	ISO 10993-1
CLINICAL	• Comparative data to DXA • Simulation Data • Clinical Data–Estimation of BMD • Clinical Data–Reproducibility • Clinical Data – Reference Data Base	• Comparative data to DXA • Simulation Data • In Vitro Data • Clinical Data–Estimation of BMD • Clinical Data–Reproducibility • Clinical Data – Fracture Risk • Clinical Data – Reference Data Base • Clinical Data – Dominant vs Non-Dominant Arm	

7. Performance Data

EchoS system has been evaluated for electrical safety, for EMC, to satisfy specific requirements for basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment, including also acoustic performances; for biocompatibility and for Software. This evaluation has been executed performing non clinical performance tests in compliance to the voluntary standards and to the FDA guidance listed below:

- AAMI/ANSI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 (IEC 60601-1:2005, Mod) (Consolidated text) Medical Electrical Equipment – Part 1: General Requirements for Safety (Iec60601-1:2005 and A1:2012)
- IEC 60601-1-2 Edition 4.0 2014-02, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests
- 60601-2-37 Edition 2.1:2015 Medical Electrical Equipment - Part 2-37: Particular Requirements For Basic Safety And Essential Performance of Ultrasonic Medical Diagnostic and Monitoring Equipment (Radiology)
- FDA Guidance "Class II Special Controls Guidance Document: Bone Sonometers - Guidance for Industry and FDA Staff" - issued on July 17, 2008
- FDA Guidance "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" - issued on September 9, 2008
- ISO 10993-1 Fourth Edition 2009-10-15 - Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process
- FDA Guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", issued June 16, 2016
- IEC 62304 First edition 2006-05, Medical device software – Software life cycle processes
- "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" – issued on May 11, 2005

Furthermore Echolight S.p.a. performed many clinical performance tests, in order to compare the clinical performances of the subject device to the performances of the X-Ray Densitometry that is a recognized gold standard for bone densitometry applications and it is used as reference device, as for the primary predicate device Ultrascan650.

The tests performed to validate the clinical performances in comparison to the reference device are listed below:

- Clinical data has been collected by Echolight on the intended patient population for the subject device, in order to create the proprietary internal database for the different ages and BMI; and in the same time verifications on reproducibility & estimation of BMD_{US} has been performed on EchoS with respect to the gold standard DXA
- in order to demonstrate the high correlation of the BMD_{US} index used by the subject device to the BMD from the gold standard DXA (BMD_{DXA}), comparative performance test of EchoS vs DXA has been performed detecting for EchoS a standard error of the estimate of 0.044 grams/cm^2 for lumbar spine and 0.038 grams/cm^2 for femoral neck measurements,

comparable with the standard error of 0.041 grams/cm^2 detected by the primary predicate device in a similar comparison test vs the same reference device.

- Simulation data and ad also real data from intended patient population are used to compare results of FRAX®original algorithm with the use of inputs from both DXA-measured femoral neck T-Score and EchoS-estimated femoral neck T-score.

8. Conclusions

In light of the evidence discussed above, the subject device has similar indications for use, patient population, technology features and performances of the predicate devices, pointing out only few differences that have been addressed by the dedicated clinical performance tests, demonstrating that the diagnostic effectiveness and accuracy on lumbar vertebrae and femoral neck of EchoS system has a significant correlation with the reference device DXA. For all these reasons, the subject device may be found substantially equivalent to the predicate devices.