Echolight S.p.A
% Giovanna De Masi
Quality, Certification and Regulatory Assistant
Via Raffaello Sanzio, 18
Lecce, Lecce 73100
ITALY

March 30, 2021.

Re: K202514
Trade/Device Name: EchoS Family
Regulation Number: 21 CFR 892.1180
Regulation Name: Bone sonometer
Regulatory Class: Class II
Product Code: MUA, OMV

Dear Giovanna De Masi:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated February 25, 2021. Specifically, FDA is updating this SE Letter as an administrative correction due to typos in the Indications for Use Statement.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Thalia Mills, OHT7: Office of In Vitro Diagnostics and Radiological Health by email (Thalia.Mills@fda.hhs.gov) or phone (301-796-6641).

Sincerely,

Michael D. O'Hara

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

Echolight S.p.A.
℅ Giovanna De Masi
Quality, Certification and Regulatory Assistant
Via Raffaello Sanzio, 18
Lecce, Lecce 73100
ITALY

February 25, 2021

Re: K202514
Trade/Device Name: EchoS Family
Regulation Number: 21 CFR 892.1180
Regulation Name: Bone Sonometer
Regulatory Class: Class II
Product Code: MUA, OMV
Dated: January 18, 2021
Received: January 21, 2021

Dear Giovanna De Masi:

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,

Michael D. O'Hara 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)*
K202514

Device Name
EchoS Family

Indications for Use *(Describe)*

1) EchoS Family is a non-invasive ultrasound (US) bone sonometer. EchoS Family works together with EchoStudio software. EchoStudio analyzes the ultrasound signals in order to compute the diagnostic parameters (BMDus, T-score, and Z-score). The BMDus 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 (BMDDXA), 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.

BMDus 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. BMDus Index has a precision comparable to that of x-ray absorptiometry, which makes it suitable for monitoring bone changes in women and men.

2) The EchoStudio software includes an optional tool called Fragility Score, which is intended to provide an assessment of 5-year fracture risk. The optional tool Fragility Score provides an estimate of 5-year probability of hip fracture and 5-year probability of a major osteoporotic fracture (clinical spine, forearm, hip or shoulder fracture). This estimate takes into account the patient's age, sex, ethnicity, height, weight, and the vertebra/femur neck ultrasound spectra and is computed using a proprietary algorithm. The tool has been validated for men and women between 30 and 90 years old.

The output is provided in a separate screen display and report that can be viewed or printed or exported to an optional physician report generator tool. The results can be used by a physician, in conjunction with other clinical risk factors, as an aid in the diagnosis of osteoporosis and medical conditions leading to increased bone fragility, and ultimately in the assessment of fracture risk.

3) EchoS Family, when used with the optional Body Composition module of EchoStudio software, is indicated to estimate total body fat percentage (%BF). EchoS Family, together with Body Composition software module, is intended to be used only on generally healthy adults and is not for diagnosis of disease or condition. Body Composition software is indicated for the calculation of the Body Mass Index (BMI) and the Basal Metabolic Rate (BMR). Body Composition software module generates a report which displays the calculated values of Body FAT, BMR, and Body Mass Index (BMI).

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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Section 5 510(k) Summary K202514

I. SUBMITTER

Applicant Information	Echolight S.p.A. Via Raffaello Sanzio, 18 73100 Lecce, Italy
Contact	dott.ssa Giovanna De Masi (Quality, Certification and Regulatory Assistant)
Date Prepared	25 august 2020

II. DEVICE

Device Trade Name	ECHOS FAMILY
Common Name	Ultrasound System
Classification Name: Regulation Number:	Bone Sonometer 21 CFR 892.1180
Classification Name: Regulation Number:	Analyzer, Body Composition, Ultrasonic 21 CFR §870.2770
Product Code	MUA and OMV

III. PREDICATE DEVICE

Legally Marketed Predicate Device (s)

510(k) Number	Pro Code	Trade Name	Applicant
K180516	21 CFR 892.1180	EchoS	Echolight S.p.a.
K082317	21 CFR 892.1170	FRAX® 10-Year Fracture Risk Software Option for GE Lunar Bone Densitometers	General Electric Co.
K082147	21 CFR 870.2770	BodyMetrix BX2000TM	IntelaMetrix, Incorporated

IV. Device Description

The EchoS Family is an ultrasound device intended primarily for the diagnosis of osteoporosis. EchoS, through the ultrasound scan of the lumbar or femoral site of interest, picks up the ultrasound signal (RF) and performs an estimate of the bone mineral density (BMD).

The device therefore allows not only the visualization of ultrasound images, but also the real-time sampling of the RF signal and its appropriate treatment to make it usable for diagnostic algorithms.

The EchoS Family consists in two different configurations: EchoS (portable version) and the EchoStation (cart version). Each version consists of two main parts: the equipment device (EchoS and EchoStation) with its own probe and the software EchoStudio.

EchoStudio is a biomedical software that, used in combination with EchoS Family, allows the evaluation of bone mineral density (BMD) by means of the proprietary method REMS (Radiofrequency Echographic Multi Spectrometry) densitometry.

By using EchoStudio, it is possible to assess the key diagnostic parameters directly on the anatomical sites with increased fracture risk, such as lumbar spine and proximal femur.

EchoStudio analyzes the ultrasound signals and echographic images in order to compute the diagnostic parameters (BMD, T-score, and Z-score) and to estimate the fracture risk by means of the Echolight diagnostic algorithms and non-ionizing technique.

V. Indication for Use

1) EchoS Family is a non-invasive ultrasound (US) bone sonometer.

EchoS Family works together with EchoStudio software. EchoStudio analyzes the ultrasound signals in order to compute the diagnostic parameters (BMDus, T-score, and Z-score).

The BMDus 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 (BMDDXA), 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.

BMDus 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.

BMDus Index has a precision comparable to that of x-ray absorptiometry, which makes it suitable for monitoring bone changes in women and men.

2) The EchoStudio software includes an optional tool called Fragility Score, which is intended to provide an assessment of 5-year fracture risk.

The optional tool Fragility Score provides an estimate of 5-year probability of hip fracture and 5-year probability of a major osteoporotic fracture (clinical spine, forearm, hip or shoulder fracture).

This estimate takes into account the patient's age, sex, ethnicity, height, weight, and the vertebra/femur neck ultrasound spectra and is computed using a proprietary algorithm.

The tool has been validated for men and women between 30 and 90 years old.

The output is provided in a separate screen display and report that can be viewed or printed or exported to an optional physician report generator tool.

The results can be used by a physician, in conjunction with other clinical risk factors, as an aid in the diagnosis of osteoporosis and medical conditions leading to increased bone fragility, and ultimately in the assessment of fracture risk.

3) EchoS Family, when used with the optional Body Composition module of EchoStudio software, is indicated to estimate total body fat percentage (%BF).

EchoS Family, together with Body Composition software module, is intended to be used only on generally healthy adults and is not for diagnosis of disease or condition. Body Composition software is indicated for the calculation of the Body Mass Index (BMI) and the Basal Metabolic Rate (BMR). Body Composition software module generates a report which displays the calculated values of Body FAT, BMR, and Body Mass Index (BMI).

VI. Comparison of technological characteristics with the predicate devices

The technological characteristics of the subject device do not raise different safety or effectiveness questions in comparison to the primary predicate EchoS K180516 because the EchoS Family includes the “EchoS” and “EchoStation” devices, respectively portable and cart version, with the relevant EchoStudio software. Compared to the primary predicate, the subject device substitutes the C3.5/60/128-Z probe with C3.5/60/128Z-3 probe. The two probes are substantially equivalent in terms of techincal specification, acoustic and thermal performances, biocompatibility, safety and EMC as reported on the attached documentation.

The “Fragility Score” software module of the subject device and the predicate K082317 are both software algorithms that require an input data set (i.e. age, sex, ethnicity, …) and provide an output estimation of fracture probability.

In terms of effectiveness, it is based on the acquisition of anthropometric data together with REMS data (BMD) to calculate a probability estimate of hip and major osteoporotic fractures (clinical spine, forearm, hip or shoulder fracture) and the related indication for use is the same of the IFU reported on the predicate K082317 (FRAX^{TM} 10-Year Fracture Risk Software Option for GE Lunar).

In terms of safety, the use of the Fragility Score module does not imply different conditions of use of the device because the required input data are the same that are normally collected during an acquisition performed with the primary predicate EchoS K180516.

The subject device and the predicate K082147 are both ultrasound devices equipped with an echographic probe which communicates with a portable or desktop computer through a USB interface. Both devices have a software module that, acquiring signals by an ultrasound device and patient anthroprometric data, provide as output the following body parameters: total body fat percentage (Body FAT), Body Mass Index (BMI) and the Basal Metabolic Rate (BMR).

In terms of effectiveness, the “Body Composition” optional module is indicated to estimate the total body fat percentage (%BF) like the analogous function performed by the predicate K082147 “BodyMetrix BX2000TM” with the related software BodyView. In addition, it is indicated, as the BodyView software, for the calculation of the Body Mass Index (BMI) and the Basal Metabolic Rate (BMR).

Therefore, the Indication for Use of the subject device is the same as that of the predicate K082147 "BodyMetrix BX2000TM".

In terms of safety, the use of the Body Composition module does not imply different conditions of use of the device because the required input data are the same that are normally collected during an acquisition performed with the primary predicate EchoS K180516.

Based on the provided information, the subject device does not raise different safety or effectiveness questions to the listed predicate devices in terms of intended use, typical clinical use, operational characteristics, and fundamental technological characteristics.

VII. Performance Data

The part in contact with patient of EchoS Family has been tested and is in compliance with:

Biocompatibility (according to ISO 10993)

The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous

Electrical Safety, Electromagnetic Compatibility EMC (according to EN 60601-1 and EN 60601-1-2)

The battery of testing included the following tests:

- Electrical Safety Test:(see attachment 15_A)
- Electromagnetic Compatibility: Test Report (see attachment 15_B)

Software Validation (According to ISO 62304)

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". The software for this device was considered as a "moderate" level of concern, since a failure or latent flaw in the software could not directly result in serious injury or death to the patient or operator.

The documentation of Software Validation can be found in the annexes of Section 14

Usability (According to IEC 62366-1:2015)

The usability of the product was conducted in accordance with IEC 62366-1:2015 and concerns various aspects of the device use.

The documentation can be found in the annexes of Section 16:

- Usability File (see Attachment 16_A)

ANIMAL STUDIES

none

PERFORMANCE TESTING - CLINICAL

Echolight, during the EchoS Family project development, carried out clinical investigations to demonstrate the safety and efficacy of the device.

Related to the first IFU claimed, two studies were conducted aimed at demonstrating that EchoS Family effectively calculates diagnostic parameters (BMDus, T-score and Z-Score) in male and female population and the age range is between 30 and 90 years old.

The first clinical trials produced a publication "Radiofrequency echographic multi spectrometry for the prediction of incident fragility fractures: A 5-year follow-up study".

The second clinical trials produced a Performance Evaluation Protocol "ECHOLIGHT: Performance Evaluation Protocol in men aged 30-90 years" and a Data Evaluation Report "ECHOLIGHT: Comparative Performance Evaluation Report Echos System Vs. DXA in a male population aged 30-90 years".

Related to the second IFU, a dedicated clinical study was conducted, aimed at demonstrating the ability of the Fragility Score (FS) parameter, calculated by an additional module of EchoStudio Software, to identify patients, men and women from 30 to 90 years old, at risk for osteoporotic fracture within 5 years.

This clinical trial is described in the documents "ECHOLIGHT: Performance Evaluation Protocol - Fragility Score Parameter" and "ECHOLIGHT: Comparative Performance Evaluation Report - Fragility Score for the assessment of fracture risk".

Related to the third IFU, three clinical studies were conducted to:

- Evaluate the feasibility and accuracy of the investigated parameter, i.e. the body fat percentage (BFP), calculated by an innovative ultrasound (US) approach, by assessing the correlation with the corresponding bioelectrical impedance analysis (BIA)-measured parameter, assumed as the reference. This clinical trial is described in the documents "ECHOLIGHT: Performance Evaluation Protocol - Body Fat Percentage" and "ECHOLIGHT: Comparative Performance Evaluation Report - Body Fat Percentage".
- Validate an innovative ultrasound (US) approach for body composition assessment, exploiting the signals acquired during a transabdominal echographic scan of a body volume in correspondence of lumbar vertebrae L1–L4 to determine the status of fat quantity and distribution. Specific attention will be paid to investigate the feasibility and accuracy of this novel approach, by assessing the correlation between basal metabolic rate (BMR) measured by the new US technology and by bioelectrical impedance analysis (BIA)-based technologies, assumed as the reference. This clinical trial is described in the documents "ECHOLIGHT: Performance Evaluation Protocol - Basal Metabolic Rate" and "ECHOLIGHT: Comparative Performance Evaluation Report - Basal Metabolic Rate".
- Validate the calculation of the body mass index (BMI) provided by a novel US-based device with respect to measurements obtained by a bioelectrical impedance analysis (BIA)-based body composition monitor and to the results obtained by a pocket calculator, taken as reference. This clinical trial is described in the documents "ECHOLIGHT: Performance

Evaluation Protocol - Body Mass Index" and "ECHOLIGHT: Comparative Performance Evaluation Report - Body Mass Index".

VIII. Conclusions

Echolight S.p.A. has determined, by using comparisons and tests, that Echos Family is substantially equivalent to the listed predicate devices in terms of intended use, typical clinical use, operational characteristics, and fundamental technological characteristics. Any differences are considered minor and do not raise new issues of the safety and effectiveness of the Echos Family device when compared to the predicate devices.