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

April 5, 2017

CyberLogic, Inc.
% Mr. Paul Dryden
Consultant
ProMedic, Inc.
24301 Woodsage Drive
BONITA SPRINGS FL 34134

Re: K161919
Trade/Device Name: UltraScan 650
Regulation Number: 21 CFR 892.1180
Regulation Name: Bone Sonometer
Regulatory Class: II
Product Code: MUA
Dated: March 29, 2017
Received: March 31, 2017

Dear Mr. Dryden:

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 on last page.

510(k) Number *(if known)*

K161919

Device Name

UltraScan 650

Indications for Use *(Describe)*

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.

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

☒ **XX** 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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CyberLogic, Inc.
611 Broadway Suite 707
New York, NY 10012

Tel – 212-260-1351

Official Contact: Jonathan J. Kaufman, President and CEO

Proprietary or Trade Name: UltraScan ™ 650

Common/Usual Name: Bone sonometer

Classification Name / Product Classification Bone sonometer
MUA, 21CFR 892.1180, Class II

Predicate Device: K103633 – GE Healthcare Achilles ultrasonometer
Reference Devices: K110646 – BeamMed – Omnisense 7000S
K023398 – Hologic QDR Model 4500

Device Description:
The *UltraScan 650* is an ultrasound device that is designed to non-invasively and quantitatively assess the amount of bone at the 1/3 location of the radius in the forearm of an individual.

The *UltraScan 650*, with a user-supplied laptop, is designed for the estimation of bone mineral density (BMD in g/cm^2) of the radius at the 1/3 location. The *UltraScan 650* outputs a BMD_{US} Index an estimate of the BMD that would be measured by dual-energy X-ray absorptiometry (DXA) at the same anatomical location, that is, an estimate of BMD_{DXA}, at the 1/3 radius. The *UltraScan 650* also outputs the T-score in standard deviations (SD) and Z-score in SD as well. The precision of the measurement is 2.1%, when expressed as a coefficient of variation. The range of the output of the *UltraScan 650*, depends on the subjects that are measured. However, based on the normative (reference) data, we can calculate the range that will include 99.85% of all subjects.

Indications for Use:
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.

Table 1 Substantial equivalence Comparison to Predicate

Attribute	**Predicate** **GE – Achilles EXPII** **K103633**	**Subject Device** **UltraScan 650**
Indications for Use	Ultrasonometer measures ultrasound variables of the os calcis to provide a clinical measure called Stiffness Index. The Stiffness Index indicates risk of osteoporotic fracture in postmenopausal women comparable to bone mineral density (BMD) as measured by X-ray absorptiometry at the spine or hip. Stiffness index results expressed as T--scores are used to assist the physicians in the diagnosis of osteoporosis in the same way as are T-scores obtained by x-ray absorpiometry. Either the stiffness index T-score or x-ray absorptiometry T-score can be utilized by a physician, in conjunction with other clinical risk factors, to provide a comprehensive skeletal assessment. The stiffness index has a precision error in older women comparable to that of x-ray absorptiometry, which makes it suitable for monitoring bone changes.	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.
Environment of Use	Hospital, sub-acute care facilities, doctor's offices and clinics	Hospital, sub-acute care facilities, doctor's offices and clinics
Patient Population	Postmenopausal women	Assess appendicular fracture risk in postmenopausal women and for determination of BMD_{US} Index in adult men and women
Fundamental technology	Ultrasound	Ultrasound
Measurement mode	Transmission	Through-transmission
Measurement location	Heel	1/3 radius
Output results	T-score Stiffness Index	T-score Z-score BMD_{US} Index

Attribute	Predicate GE – Achilles EXPII K103633	Subject Device UltraScan 650
Measurement precision	Not stated	2.1%
Measurement time	< 1 minute	15 seconds
Correlation to BMD_{DXA}	N/A	0.93
Use of normative reference x-ray absorptiometry database	No	Yes Hologic 1/3 radius adult white females and males, K023398 / K103265.
Accessories	N/A	Forearm length measuring device, elbow rest pad, and forearm positioning device.
Materials in patient contact	N/A	Surface contact, Intact Skin, Limited duration of Use per ISO 10993-1
Performance Testing		
Safety, EMC	IEC 60601-1 - Safety IEC 60601-1-2 - EMC	IEC 60601-1 - Safety IEC 60601-1-2 – EMC 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
Clinical		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

Discussion of Substantial Equivalence to Predicate

Table 1 above compares the key features of the UltraScan™ 650 with the identified predicate and it demonstrates that the proposed device can be found to be substantially equivalent. **Table 2** compares the subject device to the reference devices, specifically for the anatomical location for taking measurements and the comparison of ultrasound to DXA for a BMD_{us} Index value.

Indications for Use – The indications for use of measuring bone density.
Discussion - Both device has similar indications for use but differ in the location that the measurement is taken, however there are reference devices which take bone density measurements at the 1/3 radius, K110646.

Patient Population – The patient population is for assessing appendicular fracture risk in postmenopausal women and for determination of BMD_{US} Index in adult men and women.
Discussion - The subject device has included all individuals who may need BMD testing while the predicate is limited to postmenopausal women. We have included clinical data to support the broader population.

Environment of Use – The environment of use is hospitals, sub-acute care facilities, physician's offices, and clinics.
Discussion – There are no differences in the environment of use between the subject device and the predicate.

Technology – The technology is ultrasound via transmission utilizing multiple transducers. The subject device is placing the transducers at the 1/3 radius whereas the predicate places the transducers at the heel.
Discussion – While there is a difference in the location of the transducers between the subject device and the predicate, the reference device, K110646, BeamMed Omnisense 7000S is an ultrasound bone sonometer that is placed at the 1/3 radius. Therefore the difference between the subject device and predicate is addressed via the reference device which has similar indications for use and technology. The difference does not raise any new concerns related to substantial equivalence.

Performance – The correlation of the subject device to the gold standard DXA for measuring BMD is 0.93 vs. the reference, Hologic QDR 4500, K023398, 0.8. We did not compare performance to the predicate.
Discussion – We are making no claim of performance other than the subject device is substantially equivalent to the reference, Hologic QDR 4500, K023398. While the predicate discusses a Stiffness Index they have equated it to BMD. We believe given the higher correlation of the subject device we can present the data as BMD_{US} Index as compared to BMD_{DXA} from a marketing perspective.

Materials – The materials which are in patient contact are for less than 1 minute and would be considered as incidental.
Discussion - The type and time of patient contact to the materials is very small and poses no safety risks.

Table 2 – Substantial equivalence Comparison to the References

Attribute	Reference BeamMed Omnisense 7000S K110646	Reference Hologic QDR 4500 K023398	Subject Device UltraScan 650
Indications for Use	A non-invasive device that is designed for the quantitative measurement of the signal velocity of ultrasound waves ("Speed of Sound" or "SOS" in m/sec) propagating at multiple skeletal sites (i.e., the distal ***one-third of the radius,*** the proximal third phalanx and the fifth metatarsal). SOS provides an estimate of skeletal fragility. 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. Multiple skeletal site testing provided clinicians with alternatives if one site is not accessible and with additional skeletal information (i.e., from bones with different combinations of cortical and cancellous material and from weight bearing and non-weight bearing sites) that assists in diagnosing osteoporosis and risk fracture. The SOS measured by MiniOmni has a precision error low enough in comparison with the expected annual change in a patient's measurement to make it suitable for monitoring bone changes which occur in the early years following menopause (i.e., age range approx.. 50-65 years).	QDR X-Ray Bone Densitometers is indicated for the ***estimation of bone mineral density (BMD)***, comparison of measured variables obtained from a given QDR scan to a database of reference values, the estimation of fracture risk, vertebral deformity assessment, body composition analysis, and discrimination of bone from prosthetics using the Hologic QDR X-Ray Bone Densitometers	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.
Environment of Use	Hospital, sub-acute care facilities, doctor's offices and clinics	Hospital, sub-acute care facilities, doctor's offices and clinics	Hospital, sub-acute care facilities, doctor's offices and clinics

Attribute	Reference BeamMed Omnisense 7000S K110646	Reference Hologic QDR 4500 K023398	Subject Device UltraScan 650
Patient Population	Females 50-65 years old	Not specified	Assess appendicular fracture risk in postmenopausal women and for determination of BMD_{US} Index in adult men and women
Fundamental technology	Ultrasound	X-ray	Ultrasound
Measurement mode	Axial Transmission	X-ray	Through-transmission
Measurement location	Distal radius	1/3 radius	1/3 radius
Output results	T-score Z-score SOS	T-score Z-score BMD_{DXA}	T-score Z-score BMD_{US} Index
Measurement precision	Not stated	Not stated	2.1%
Measurement time	< 1 minute	< 1 minute	15 seconds
Correlation to BMD_{DXA}	N/A	0.8	0.93
Use of normative reference x-ray absorptiometry database	No	Yes	Yes
Accessories	N/A	N/A	Forearm length measuring device, elbow rest pad, and forearm positioning device.
Materials in patient contact	N/A	N/A	Surface contact, Intact Skin, Limited duration of Use per ISO 10993-1
Performance Testing			
Safety, EMC	IEC 60601-1 - Safety IEC 60601-1-2 - EMC	IEC 60601-1 - Safety IEC 60601-1-2 - EMC	IEC 60601-1 - Safety IEC 60601-1-2 – EMC 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
Clinical			Comparative data to DXA Simulation Data, In Vitro Data Clinical Data – Estimation of BMD, Reproducibility, Fracture Risk, Reference Data Base, Dominant vs Non-Dominant Arm

Discussion of Substantial Equivalence to Reference Devices

The *UltraScan 650* is viewed as substantially equivalent to the predicate device because:

Indications for Use – The indications for use of measuring bone density.
Discussion - All devices have similar indications for use and can be found substantially equivalent.

Patient Population – The patient population is for assessing appendicular fracture risk in postmenopausal women and for determination of BMD_{US} Index in adult men and women.
Discussion - The subject device has included all individuals who may need BMD testing while the references are limited to postmenopausal women. We have included clinical data to support the broader population.

Environment of Use – The environment of use is hospitals, sub-acute care facilities, physician's offices, and clinics.
Discussion – There are no differences in the environment of use between the subject device and the references.

Technology – The technology is ultrasound while one reference uses ultrasound the other uses X-ray, all take the measurements at the 1/3 radius or distal radius which includes the 1/3 radius.
Discussion – While there is a difference in the technology for the K023398 DXA reference, we compared our clinical performance to this reference and found a significant correlation.
The difference does not raise any new concerns related to substantial equivalence.

Performance – The correlation of the subject device to the gold standard DXA for measuring BMD is 0.93 vs. the reference, Hologic QDR 4500, K023398, 0.8.
Discussion – We are making no claim of performance other than the subject device is substantially equivalent to the reference, Hologic QDR 4500, K023398. While the predicate discusses a Stiffness Index they have equated it to BMD. We believe given the higher correlation of the subject device we can present the data as a BMD_{US} Index as compared to BMD_{DXA} from both a scientific and from a marketing perspective.

Non-Clinical Testing Summary –
We performed testing which evaluated:

- AAMI/ANSI/ES60601-1:2005 for electrical safety
- IEC 60601-1-2:2007 for EMC
- Distance Validation;
- Time Delay Correction; and
- Quality Control
- Acoustic output

Cinical Testing Summary –

The *UltraScan 650* has been tested against several data sets to demonstrate the efficacy of the *UltraScan 650*. The data are:

- Simulation Data;
- In Vitro Data;
- Clinical Data – Estimation of BMD;
- Clinical Data – Reproducibility;
- Clinical Data – Fracture Risk;
- Clinical Data – Reference Data Base; and
- Clinical Data – Dominant vs Non-Dominant Arm

Discussion of Differences –
The differences presented and discussed above are:

- Patient population
- Comparison and correlation of the *UltraScan 650* quantitatively estimates the bone mineral density (BMD) as measured by dual-energy x-ray absorptiometry (DXA), i.e., BMD_{DXA} Index. We found the correlation to be 0.93 vs. the reference of 0.8.

These differences based upon the testing and risk assessment do not raise new concerns of safety and thus the subject device can be considered as substantially equivalent to the predicate.

Substantial Equivalence Conclusion -
Based upon the presented information the sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to be substantially equivalent and there are no new concerns raised.