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

January 9, 2017

Bone Index Finland, Ltd.
% Janne Karjalainen
Chief Technology Officer (CTO)
Microkatu 1
Kuopio 70211
FINLAND

Re: K161971
Trade/Device Name: Bindex BI-2
Regulation Number: 21 CFR 892.1180
Regulation Name: Bone sonometer
Regulatory Class: II
Product Code: MUA
Dated: July 12, 2016
Received: December 15, 2016

Dear Janne Karjalainen:

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)*
K161971

Device Name
Bindex BI-2

Indications for Use *(Describe)*
Bindex measures apparent cortical bone thickness at the proximal tibia and can be used in conjunction with other clinical risk factors or patient characteristics as an aid to the physician in the diagnosis of osteoporosis and other medical conditions leading to reduced bone strength and in the determination of fracture risk.

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.

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510(k) Summary

I. SUBMITTER

Bone Index Finland, Ltd.
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Phone: +358 45 896 2650
Contact Person: Janne Karjalainen
Date Prepared: 2 Dec, 2016

II. DEVICE

Name of Device: Bindex BI-2
Common or Usual Name: Bone sonometer
Classification Name: Bone sonometer (21 CFR 892.1180)
Regulatory Class: II
Product Code: MUA

III. PREDICATE DEVICE

Bindex BI-100 bone sonometer, K152020.

This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The Bindex BI-2 system consists of handheld ultrasound transducer and software. Bindex BI-2 is connected to the USB port of a computer and controlled with computer software. Bindex BI-2 is used for measurement of cortical bone thickness and it provides Density Index (DI), a parameter which estimates bone mineral density at the hip as measured with DXA. For measurements, gel is applied on skin and ultrasound transducer is manually placed on the measurement location. Standardized measurement location is at proximal tibia (1/3 length of tibia). Transducer is manually oriented perpendicularly to the surface of the cortical bone to achieve accepted measurement. Measurement is repeated five times at each measurement location. Finally, transducer is disinfected by wiping gel off with isopropyl alcohol moistened cloth.

The associated accessories include:

- Measurement stick
- Ultrasound gel (optional)

V. INDICATIONS FOR USE

Bindex measures apparent cortical bone thickness at the proximal tibia and can be used in conjunction with other clinical risk factors or patient characteristics as an aid to the physician in the diagnosis of osteoporosis and other medical conditions leading to reduced bone strength and in the determination of fracture risk.

Indications for use discussion

The Indications for Use statement for the Bindex BI-2 is identical to the predicate device; thus raises no additional questions on safety and effectiveness.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The predicate and subject devices are based similar ultrasound technology and are based on the same measurement principle. The main differences between the devices are structural in terms mechanics and electronics. Importantly, the transducer (responsible for conversion of electrical energy to kinetic mechanical energy), is the same for both devices.

The predicate and subject devices are compared in table 1.

Table 1. Device comparison table.

#	Item	Bindex BI-100 (Predicate)	Bindex BI-2 (subject)
1	Indications for use	Bindex measures apparent cortical bone thickness at the proximal tibia	Same

		and can be used in conjunction with other clinical risk factors or patient characteristics as an aid to the physician in the diagnosis of osteoporosis and other medical conditions leading to reduced bone strength and in the determination of fracture risk.	
2	Measurement mode	Apparent Cortical Thickness (Ct.Th.).	Same
3	Probe compatibility	One transducer, centre frequency = 3.0 MHz (nominal)	Same
4	Electrical safety	IEC 60601-2-37:2001 including Amendments 1 and 2; and IEC 60601-1:2005	Same
5	Electromagnetic compatibility	Complies with IEC 60601-1-2:2007	Same
6	Power supply	PC USB port powered.	Same
7	Operating Environment	Temperature: +10˚C to +40˚C Humidity: 5% to 85% RH, non-condensing Atmospheric Pressure: 600 to 1060 Pc	Same
8	Storage Environment	Temperature: +10˚C to +40˚C Humidity: 5% to 85% RH, non-condensing	Same
9	Calibration	Calibration before each use.	Same

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the Bindex BI-2 device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 “Use of International Standard ISO-10993,‘Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,’”May 1, 1995, and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices −Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA. The battery of testing along the ISO 10993-1 would recommend the following tests:

- Cytotoxicity
- Sensitization
- Irritation

The Bindex BI-2 is in skin contact for duration of less than 24 hours. Since the use of Bindex involves very short skin contact (typically less than 10 minutes) on a healthy skin and therefore poses a very low risk. Safety of the manufacturing and used materials has been further discussed in Biocompatibility report (Section 13).

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the measurement system, consisting of the Bindex BI-2 and a laptop computer (on battery use or connected to power supply with isolation transformer). The system complies with the IEC 60601-1, and IEC 60601-2-37 standards for safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing

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.

Mechanical and acoustic testing

The acoustic output and mechanical properties have been tested along the principles presented in harmonized standards IEC 62359 and IEC 60601-1:

- Acoustic Testing has been conducted on the predicate device and test documentation in this submission shows equivalence of the devices on behalf of acoustic output.
- Drop test (hand piece dropped from 1m on hard surface).
- Ball pressure test (pressed with steel ball 5mm in diameter with force of 20N one hour at a temperature of 75±2˚C)
- Moulding stress relief (device placed in circulating air oven at 70 ˚C for 7 hours and let cool down)

Clinical Studies

The same clinical and pre-clinical data supports the safe and effective use of Bindex BI-2 as with Bindex BI-100, to which substantial equivalence is shown.

The safety and effectiveness of Bindex BI-2 device has been discussed in clinical evaluation document Section 16.

VIII. CONCLUSIONS

The related safety standards are the same for the predicate and subject device. The same clinical evidence applies to both devices. In the present submission, the performance testing comparing the two models shows that the subject device is substantially equivalent to the predicate device and does not raise additional questions on safety or effectiveness.

Date: 12 / 02 / 2016
mm / dd / year

Janne Karjalainen, CTO, Bone Index Finland Ltd.