Bone Index Finland Ltd.
Janne Karjalainen
CTO
Savilahdentie 14
Kuopio 70700
FINLAND

Re: K211350
Trade/Device Name: Bindex BI-2
Regulation Number: 21 CFR 892.1180
Regulation Name: Bone Sonometer
Regulatory Class: Class II
Product Code: MUA
Dated: April 13, 2022
Received: April 21, 2022

April 29, 2022

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. 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,

Jessica Lamb, Ph.D.
Assistant 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)*
K211350

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

K211350

510(k) Summary

SUBMITTER

Bone Index Finland Ltd.
Savilahdentie 14
Kuopio, Finland 70700
Establishment registration number: 3013328880
Phone: +358 45 896 2650
Contact Person: Janne Karjalainen
Date Prepared: April 24th, 2022

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

I. 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)

II. PREDICATE DEVICES

Predicate devices:

(1) Bindex BI-2 model (K161971).

III. DEVICE CHANGE COMPARISON

Changes to legally marketed device are described in Table 1.

Table 1. Device comparison table for currently marketed Bindex BI-2 and modified version.

#	Item	Bindex BI-2 (Legally marketed, K161971)	Bindex BI-2 (Modified, subject device)
1	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.	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.
2	Intended use	Bindex measures apparent cortical bone thickness at the upper shaft of tibia (See Figure 1) and reports diagnostic parameter, Density Index (DI), an estimate of hip Bone Mineral Density measured with gold standard Axial DXA. Thresholds for osteoporosis for DI have been determined in comparison to DXA. The DI reported by Bindex is used as an aid in osteoporosis diagnostics by applying pre determined thresholds. DI can help the clinician in estimation of fracture risk. After the measurement, Bindex® software gives an estimation of the presence of osteoporosis marked in the color bar: Green (Low Probability of Osteoporosis), Yellow (Additional Investigations Needed) or Red area (High Probability of Osteoporosis). A total of 90% of osteoporotic patients diagnosed by hip BMD are in the yellow or red area (90% sensitivity) and 90% of non osteoporotic	Bindex measures apparent cortical bone thickness at the upper shaft of tibia (See Figure 1) and reports diagnostic parameter, Density Index (DI), an estimate of hip Bone Mineral Density measured with gold standard Axial DXA. Thresholds for osteoporosis for DI have been determined in comparison to DXA. The DI reported by Bindex is used as an aid in osteoporosis diagnostics by applying pre determined thresholds. DI can help the clinician in estimation of fracture risk. After the measurement, Bindex® software gives an estimation of the presence of osteoporosis marked in the color bar: Green (Low Probability of Osteoporosis), Yellow (Additional Investigations Needed) or Red area (High Probability of Osteoporosis). A total of 90% of osteoporotic patients diagnosed by hip BMD are in the yellow or red area (90% sensitivity) and 90% of

		patients are in the green or yellow area (90% specificity). Statistically at least 80% sensitivity and specificity for hip osteoporosis will be reached with 95% confidence. Patient classification is based on thresholds (separating red/yellow/green areas) published in a study by Karjalainen et al. "New method for point of care osteoporosis screening and diagnostics" in Osteoporosis International 2016. Currently the use of Bindex® DI thresholds are validated for Caucasian women at the age between 50 to 90 years. Bindex® measurement takes about one minute. Bindex® device should be operated by a physician, or under supervision of physician by a nurse, pharmacist or trained person with a suitable background education and skills.	non osteoporotic patients are in the green or yellow area (90% specificity). Statistically at least 80% sensitivity and specificity for hip osteoporosis will be reached with 95% confidence. Patient classification is based on thresholds (separating red/yellow/green areas) published in a study by Karjalainen et al. "New method for point of care osteoporosis screening and diagnostics" in Osteoporosis International 2016. Currently the use of Bindex® DI thresholds are validated for Caucasian and Hispanic women at the age between 50 to 90 years. Bindex® measurement takes about one minute. Bindex® device should be operated by a physician, or under supervision of physician by a nurse, pharmacist or other health professional who has gone through training. Bindex should not be used by patients.
3	Measurement mode	Cortical Thickness (Ct.Th.).	Same
4	Probe compatibility	One transducer, centre frequency = 3.0 MHz (nominal)	Same
5	Electrical safety	IEC 60601-2-37:2001 including Amendments 1 and 2; and IEC 60601-1:2005	Same
6	Electromagnetic compatibility	Complies with IEC 60601-1-2:2007	Updated to IEC 60601-1-2 Edition 4.0, 2014
7	Power supply	PC USB port powered.	Same
8	Operating Environment	Temperature: +10˚C to +40˚C Humidity: 5% to 85% RH, non-condensing Atmospheric Pressure: 600 to 1060 Pc	Temperature: +15˚C to +40˚C Humidity: 5% to 90% RH, non-condensing Atmospheric Pressure: Same
9	Storage Environment	Temperature: +10˚C to +40˚C Humidity: 5% to 85% RH, non-condensing	Temperature: +15˚C to +40˚C Humidity: 5% to 90% RH, non-condensing Atmospheric Pressure: Same
10	Calibration	Calibration before each use.	Same

IV. PERFORMANCE DATA SUMMARY

This section describes the performance data generated to show safe and effective use of Bindex BI-2 device. The data for the use in home healthcare environment is summarized in table 2. and described below in more detail.

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.

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). 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" and "Content of Premarket Submissions for Management of Cybersecurity 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 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)

Table 2. Performance data summary, home healthcare environment.

Device Change	**Risks**	**Verification/Validation Methods**	**Acceptance Criteria**	**Summary of Results**
Use in home healthcare environment	Electromagnetic interference	IEC 60601-1-2 Edition 4.0 Conducted disturbances induced by RF fields, Test method IEC 61000-4-6 Radiated radio frequency (RF) electromagnetic fields (EM) , Test method IEC 61000-4-3	Essential performance and Basic Safety maintained.	Test samples passed the tests with intact Essential Performance and Basic Safety
	Environmental hazards	Tests in accordance to IEC 60601-1:2005 +Am1:2012; Clause 5.7, 8.8.3 and 8.7 IEC 60601-1-11:2015; Clause 4.2.2, 4.2.3.1, 8.3.1 and 10.1.2	Essential performance and Basic Safety maintained.	Test samples passed the tests with intact Essential Performance and Basic Safety

EMC testing according to IEC 60601-1-2 Edition 4.0, 2014:

- Changes in required test for Conducted disturbances induced by RF fields, Test method IEC 61000-4-6
- Changes in required tests for Radiated radio frequency (RF) electromagnetic fields, Test method IEC 61000-4-3

Home healthcare environment standard IEC 60601-1-11:2015 and main safety standard IEC 60601-1:2005 related tests have been conducted.

Expanding the population in the Intended Use statement to include Hispanic individuals:

- A clinical trial has been conducted in Albuquerque, New Mexico, USA to investigate whether the Density Index thresholds used with Bindex BI-2 device need adjustments when applied in Hispanic population. The method and protocol for this study are same as used in previous clinical studies supporting the use of legally marketed device Bindex BI-2 (K161971), and well-established (several publications, suggested by International society for clinical densitometry). Key findings are summarized below, as written in publication by E. Lewiecki (J Clin Densitom 2020):
  " The study enrolled 293 postmenopausal women (153 Caucasian, 140 Hispanic) with and without osteoporosis. The sensitivity and specificity for DI thresholds to distinguish women with total hip or femoral neck T-score ≤-2.5 or > -2.5 was similar in Caucasians (sensitivity 80%, specificity 86%) and Hispanics (sensitivity 80%, specificity 91%). The findings of this study confirm the utility of previously established DI thresholds to identify women who are likely or unlikely to have osteoporosis and suggest that the same thresholds can be used for postmenopausal Caucasian and Hispanic women."
- The results are similar than those found in previous study by Schousboe et al. published in Osteoporos Int 2016, (Sensitivity 80% and specificity 82%). These results were included in previous submission for the legally marketed device (K161971).

The labelling of the Bindex BI-2 have been changed to reflect above described additions in use environment and addition of Hispanic ethnicity to intended population.

V. CONCLUSIONS

The Bindex BI-2 product has been reviewed for risks arising from the change of device use environment from PROFESSIONAL HEALTHCARE to HOME USE, in which the safe use is verified by tests. The changes in Bindex BI-2 described in this submission do not raise additional questions relating to safety and efficacy of the device. Thus, the device remains substantially equivalent to the previously cleared Bindex BI-2 device.