OCT 24 2008

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: March 11, 2007

1. Company and Correspondent making the submission:

Name – Krell Precision (Yang Zhou) Co., LTD
Address – Number 28, Xing Yang Road, Yang Zhou, Jiang Su Province, China
Telephone – +86(0)514-87961819
Fax – +86(0)514-87961918
Contact – Mike Zheng
Email – mike_zheng@krellprecision.com

2. Device :

Trade/proprietary name: KRELL WEIGHT AND BODY FAT SCALE/BFA-8530
Common Name : Analyzer, Body Fat
Classification Name : Impedance plethysmograph

3. Predicate Devices :

Tanita BC-533, (K040778); Bonso Health o meter BMF583

4. Classifications Names & Citations :

21CFR 870.2770, MNW, Body Fat Analyzer, Class2

5. Description :

5.1 General

The patient steps on the scale device, where two electrodes are located. The patient must step on the electrodes with bare feet, with normal moisture. Through harmless current stimulation of 500 μA, at 50 kHz, the Krell Body Fat Analyzer calculates the body fat percentage. This calculation is done via the Bioelectrical Impedance Method. The current is passed through the body and the impedance of the body determines the body fat. The calculation is based upon electrical impedance, height, weight, age, and gender. The calculation is performed via internal software, which uses the variables programmed in by the user. There are elements of this process that can produce erroneous readings, such as dry feet or improper-programmed data. The User's Manual defines items which could cause erroneous readings.

This bioelectrical impedance method has been validated via DXA (Dual Energy X-Ray Absorptiometry).

5.2 Direction

As discussed in the General description, the Krell Body Fat Analyzer is relatively simple to use. The user inputs the variable data of age, height, and gender. The user steps onto the scale and the devices measures the user weight and body impedance (via the Bioelectric Impedance through the two electrodes on the scale). The scale displays the user's body fat composition. Upon the user's selection, the device can also display the user's weight.

6. Indication for use :

The KRELL Weight & Body Fat Monitoring Scale is indicated to measure body weight and impedance and estimate the percentage of Body Fat and body water, Bones mass using BIA (bioelectrical impedance analysis). This product is for use by generally healthy adults and children (from age 10 and up) who are not ill, feverish, have a chronic or acute disease, or a condition that affects the level of hydration such as pregnancy.

7. Comparison with predicate device :
Krell Precision (Yang Zhou) Co., LTD, believes that the Krell Weight and Body Fat Scale is substantially equivalent to the Tanita BC-533 (K040778), Bonso Health o meter Model BFM583 (K030349)

8. Safety and Performance Data :

Electrical, mechanical, environmental safety and performance testing according to standard EN/IEC 60601-1. Clinical testing was used to validate the effectiveness and accuracy of the device. All test results were satisfactory.

9. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Krell. Inc. concludes that The Krell Weight and Body Fat Scale is safe and effective and substantially equivalent to predicate devices as described herein.

10. Krell Precision (Yang Zhou) Co., LTD will update and include in a summary any other information deemed seasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 24 2008

Krell Precision (Yang Zhou) Co., Ltd.
c/o Mr. Charles Mack
Principal Engineer
International Regulatory Consultants, LLC
340 Shady Grove Road
FLINTVILLE TN 37335

Re: K081587
Trade/Device Name: KRELL Weight & Body Fat Monitoring Scale, Model BFA-8530
Regulation Number: 21 CFR §870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: MNW
Dated: October 12, 2008
Received: October 20, 2008

Dear Mr. Mack:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

Indications for Use
510(k) Number (if known): K081587

Device Name:
Weight & Body Fat Monitoring Scale
(Model BFA-8530)

Indications For Use:

The KRELL Weight & Body Fat Monitoring Scale is indicated to measure body weight and impedance and estimate the percentage of Body Fat and body water, Bones mass using BIA (bioelectrical impedance analysis). This product is for use by generally healthy adults and children (from age 10 and up) who are not ill, feverish, have a chronic or acute disease, or a condition that affects the level of hydration such as pregnancy.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K081587