K020738
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510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance ith the requirements of SMDA and 21 CFR §807.92

1.0 Submitter's Name: AViTA Corp
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Contact: Mr. Geo Lin, General Manager

MAY 22 2003

2.0 Device Name: **AViTA BF 1 BODY FAT ANALYZER**
Models

3.0 Classification: Class II

4.0 Predicate Device: **AViTA BF1(Vitalio) Body Fat Analyzer** has similar general design with **Omron HBF-306 Body Fat Aalyzer(K011652)marketed by Omron Healthcare INC.**

5.0 Device Description: **AViTA BF1(Vitalio) Body Fat Analyzer** is a hand-held, non-sterile, reusable Body Fat Analyzer intended for estimation of the body fat of percentage in the home.

6.0 Intended Use: The **AViTA Body Fat Analyzer** is intended for estimation of the body fat of percentage in the home.

7.0 Performance Summary: In terms of operating specification, Safety & EMC requirements, the device conforms to applicable standards included IEC 60601-1 and IEC 60601-1-2 requirements. Moreover, A comparison study with device that use DEXA(Dual energy X-ray absorptiometry) technology was performed to validate the performance of the **AViTA BF1(Vitalio) Body Fat Analyzer.** Subjects were grouped as male/ female, ages. The comparison study demonstrated that the clinical repeatability of **AViTA BF1(Vitalio) Body Fat Analyzer** is statistically and clinically acceptable in all age/weight/height groups.

8. Conclusions:

The **AViTA BF1(Vitalio) Body Fat Analyzer** have the same intended use and similar technological characteristics as **Omron HBF-306 Body Fat Aalyzer(K011652)marketed by Omron Healthcare INC.**. Moreover, bench testing contained in this submission and clinical testing supplied demonstrate that any differences in their technological characteristics do not raise and new questions of safety or effectiveness. Thus, the **AViTA BF1(Vitalio) Body Fat Analyzer** is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2003

AVITA Corporation
c/o Ms. Jennifer Reich
Harvest Consulting Corporation
3892 South America West Trail
FLAGSTAFF AZ 86001

Re: K020738
Trade/Device Name: BFI (Vitalio) Body Fat Analyzer
Regulation Number: 21 CFR §870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: 74 MNW
Dated: January 30, 2003
Received: February 25, 2003

Dear Ms. Reich:

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 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 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:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment B

510 (k) NUMBER (IF KNOWN): K020738

DEVICE NAME: **AviTA BF1(Vitalio) Body Fat Analyzer**
AViTA Corp.

INDICATIONS FOR USE:

The device is a noninvasive bioimpeadance analyzer used to estimate body fat percentage in home use. The device is for normal, healthy person only, and the applicable age range is 20 to 80 years old.

The device is to be used in the ENVIRONMENT of room temperature & normal environment condition.

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

Concurrence of CDRH, Office of Device Evaluation

Prescription Use _____ OR Over-The-Counter V
(Per 21 CFR 801.109) (Optional Format)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020738