K073334
PAGE 1 OF 3

510K Summary

Date: 11/14/2007

AUG 22 2008

Multiwell

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Contact Person: Mr. Philippe Dijol

Sec 5.1 – Summary Information

Submission Correspondent:	Christine Valmy Inc.
Address:	285 Changebridge Road Pine Brook, NJ 07058
Phone:	973-575-1050
Fax:	973-227-5646
Contact:	Mr. Peter de Haydu
Submission Sponsor:	Multiwell machines
Date Prepared:	11/14/2007
Trade Name:	Ohmniscan NG
Common Name:	Analyzer, Body Composition
Classification:	Class II
Panel:	Cardiovascular
Regulation #:	870.2770
Product Code:	MNW

Sec 5.2- Device Description:

Ohmniscan NG is a high performance portable bioimpedance measuring device that enables evaluation of daily energy needs, fat mass (in % of total weight and in kg), lean mass (in kg) hydric condition (in % of total weight and in kg), body mass index, using a painless micro current technique.

It is used for the initial assessment and for treatment monitoring. Regular check allows fat loss to be monitored and the results are used as a highly motivational tool.

Ohmniscan NG releases a very low intensity alternating current at a 50 KHz frequency, by applying the four polar methods to measure the body resistance. This measurement determines the client's impedance.

Ohmniscan NG enables the creation of 100 customer cards with upto 8 measurements of the customer, their records, the interpretations, and the comparison between 2 measurements of the same client. It enables the creation of a customer file with surname, first name, sex, race, age, height, weight, activity, date of measurement, interpretation, and comparisons. Its fast measuring function allows calculations to be made in a minimum amount of time and they can be interpreted later. The unit comes complete with pen, connection wires and electrodes. The device is delivered with printer for ticket results.

Sec 5.3-Intended Use

The main intended uses of Ohmniscan NG is to deduce:

- Impedance(Z in ohms)
- Total body water(TBW in L and in %)
- Lean Mass(LM in KG)
- Fat Mass(FM in KG and %)
- Basal Metabolism(Kcal)
- Daily energy needs(Kcal)
- B.M.I.(Basal Mass Index).

Sec 5.4- Predicate Devices

The predicate device referenced in this submission is:

Bodystat Ltd.
Po Box 50.
Douglas Isle Of Man
British Isles, BR IM99 1 DQ
Bodystat
K 002835

Sec 5.5- Summary and Conclusion Regarding Substantial Equivalence:

By definition, a device is substantially equivalent when the device has the same intended use and the same technological characteristics as the predicate device, or has the same intended use and different technological characteristics, but it can be demonstrated that the device is as safe and effective as the predicate device and the new device does not raise different questions regarding safety and effectiveness as compared to the predicate device.

Besides the point that Ohmniscan NG comes with the printer for ticket results, there are no differences between the Multiwell Machine, Ohmniscan NG and the predicate device specifications, and therefore no new issues are raised regarding safety and effectiveness. There are no differences in the technological characteristics or in the intended use of these devices.

The Ohmniscan NG device is identical to the predicate device,
and therefore we have determined this device to be substantially equivalent to the referenced predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 22 2008

Mr. Peter de Haydu
President
Christine Valmy, Inc.
285 Change Bridge Road
PINE BROOK NJ 07058

Re: K073334
Trade/Device Name: Ohmniscan NG
Regulation Number: 21 CFR §870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: II
Product Code: MNW
Dated: August 19, 2008
Received: August 20, 2008

Dear Mr. Haydu:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(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 Biometric's (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,

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

K073334

Ohmniscan NG

Indication for use:

Ohmnsiscan NG is a non prescription device and is used on healthy subjects with no known disease or condition, and is identified as used for generally healthy adults (18-65). It is used to estimate the following:

- Impedance(Z in ohms)
- Total body water (TBW in L and in %)
- Lean Mass(LM in KG)
- Fat Mass (FM in KG and %)
- Basal Metabolism(Kcal)
- Daily energy needs(Kcal)
- B.M.I. (Body Mass Index).

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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K073334