JUN 2 5 2003

SUMMARY

This summary of 510K safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. APPLICANT INFORMATION

a. Company Name:	Clio Designs Incorporated
b. Company Address:	63 Herrick Rd. Newton Centre, MA 02459
c. Company Phone:	617-969-7509
d. Contact Person:	Bernard Fabricant Vice President
e. Date of Summary:	11/10/02

2. DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	SmartShape Body Composition Analyzer 4010
b. Classification Name:	Body Composition Analyzer 21 CFR 870.2770 MNW
c. Device Class:	Class II

3. IDENTIFICATION OF PREDICATE DEVICE

a. Company:	Omron Healthcare, Inc.
b. Device:	Body Fat Analyzer Model HBF-306
c. 510K No.:	K011652
d. Date Cleared:	11/07/01

4. DEVICE DESCRIPTION

The SmartShape Body Composition Analyzer is a hand-held device designed to determine body fat composition. The device offers the user the ability to measure their body fat level and store the data for analysis. It is programmable for up to 10 separate individuals and uses bioelectric impedance technology for the estimation of percent body fat. The device also includes a clock and alarm function.

5. SUBSTANTIAL EQUIVALENCE

The SmartShape Body Composition Analyzer is substantially equivalent to the Omron Healthcare, Inc. Body Fat Analyzer Model HBF-306.

The fundamental technical characteristics and indications for use of the SmartShape Body Composition Analyzer are similar to those of the predicate device. Both devices use bioelectric impedance for the estimation of percent body fat. The body composition analyzer and the predicate devices are indicated for personal home use.

6. INDICATIONS FOR USE

The SmartShape Body Composition Analyzer is a noninvasive bioimpedance analyzer intended for use in the estimation of percent body fat by body weight.

7. TECHNOLOGICAL CHARACTERISTICS

The SmartShape Body Composition Analyzer is a programmable hand-held device designed to determine body fat composition. The device utilizes the technology of bioelectric impedance to determine the transmission speed of a low level electrical current through the user. The device software utilizes the impedance data, patient weight, gender, age, and height data to calculate the patient percent body fat.

A comparison of the technological characteristics and performance testing of the SmartShape Body Composition Analyzer to those of the predicate device reveals that the devices are substantially equivalent.

8. PERFORMANCE DATA

Performance testing was conducted on the SmartShape Body Composition Analyzer for functionality, reliability, repeatability and reproducibility. All results were shown to be acceptable. In addition, coparison testing was performed using the SmartShape Body Composition Analyzer and the predicate device. Results of the testing showed that the SmartShape Body Composition Analyzer was equivalent in performance to the predicate

device. The SmartShape Body Composition Analyzer was shown to perform as intended.

9. 510(K) CHECKLIST

This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 25 2003

Mr. Bernard Fabricant
Vice President
Clio Designs Incorporated
63 Herrick Road
NEWTON CENTRE, MA 02459

Re: K023817
Trade/Device Name: SmartShape™ Body Composition Analyzer 4010
Regulation Number: 21 CFR §870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: 74 MNW
Dated: March 23, 2003
Received: March 27, 2003

Dear Mr. Fabricant:

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 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 the 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" (21CFR Part 807.97) you may obtain. 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

INDICATIONS FOR USE STATEMENT

Applicant's Name: **Clio Designs Incorporated**

Device Name: **SmartShape Body Composition Analyzer 4010**

The SmartShape Body Composition Analyzer is a noninvasive bioimpedance analyzer intended for use in the estimation of percent body fat by body weight.

Over-the-Counter Use ✓

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K023817