

9. 510(k) Summary

FEB 24 2003

510(k) SUMMARY
YAMATO ClockMINI and ClockNAVI BODY FAT MONITORS

SUBMITTER INFORMATION

Company name / address: Enscicon Corporation
518 17th Street
Suite 1350
Denver, CO 80202

Contact name / numbers: Clay Anselmo
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Date summary prepared: October 22, 2002

DEVICE IDENTIFICATION

Trade names: Yamato ClockMINI Body Fat Monitor, DF301
Yamato ClockNAVI Body Fat Monitor, DF311

Common name: Body Fat Analyzer

Classification name: Impedance Plethysmograph

PREDICATE DEVICE

Trade name: Omron HBF-306 Body Fat Analyzer

510(k) number: K011652

DEVICE DESCRIPTION

The Yamato ClockMINI Body Fat Monitor – DF301 (ClockMINI) is an over-the-counter body composition analyzer and clock that uses Bioelectrical Impedance Analysis (BIA) to estimate body fat percent by measuring the electric resistance sensed when a 50kHz/500 μ A current is passed through the body. From this measurement the device uses an algorithm to display an estimate of body fat percent. In addition, the ClockMINI classifies the body fat percent into one of four categories: low, average, high, and very high.

The Yamato ClockNAVI Body Fat Monitor – DF311 (ClockNAVI) is an over-the-counter body composition analyzer and clock that uses Bioelectrical Impedance Analysis (BIA) to measure body fat percent by measuring the electric resistance sensed when a 50kHz/500 μ A current is passed through the body. From this measurement the device uses an algorithm to display an estimate of body fat percent and a classification of obesity level. The device also calculates Body Mass Index (BMI) from data input by the user and displays an obesity level classification based on the calculated BMI.

INDICATIONS FOR USE

The Yamato ClockMINI and ClockNAVI Body Fat Monitors are intended for use in the estimation of body fat percent in users between the ages of 10 and 80 years old.

TECHNOLOGICAL CHARACTERISTICS COMPARISON

Both of the Yamato devices and the Omron device are battery powered (2 “AAA” batteries) and pass a small electrical current (~500 μ A, 50kHz) through the hands, arms, and upper torso of the user for the purpose of calculating the bio-electrical impedance of the user. This method is commonly referred to as bio-electrical impedance analysis (BIA.)

The primary indication for use for the Yamato devices and the Omron device is the estimation of body fat percent. The intended user group for all of the devices for normal subjects is 10 to 80 years. (The Omron device has an “athlete” mode that is not present in the Yamato devices.) The technological characteristics for all the devices are equivalent including the method for estimating body fat percent and the method for calculating body mass index (BMI).

The following primary characteristics of the two Yamato devices are equivalent to the Omron device.

- Method for estimating body fat percent (BIA)
- Calculation for Body Mass Index (BMI)
- Current and Frequency specifications
- Route of current through the body
- Data input (height, weight, age, gender)
- Output parameters (BMI (ClockNAVI only), Body Fat%)

PERFORMANCE DATA

To show acceptable performance of the Yamato ClockMINI and ClockNAVI devices for estimating body fat percentage, the devices were compared in a Yamato study against the under water weighing (UWW) method. Fifty-one males and 98 females had their body fat percentages estimated by both methods. The two methods provided very similar results overall. In both the male and female populations, the average difference between the Yamato device and the UWW method was extremely small (0.1% m, and -0.2% f) and the standard deviation of the difference was between 3.2% and 3.3%. When considering the variability associated with both methods, including measurement of residual volume in the lung, unpredictability of body water, and the estimation of intestinal tract volume, these numbers are quite small.

CONCLUSION

The Yamato ClockMINI and ClockNAVI Body Fat Monitors are substantially equivalent to the Omron HBF-306 Body Fat Analyzer.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Yamato Corporation
c/o Mr. Clay Anselmo
Submission Correspondent
Encicon Corporation
518 17th Street
Suite 1350
DENVER CO 80202

FEB 24 2003

Re: K023942

Trade/Device Name: Yamato ClockMINI Body Fat Monitor, DF301; and
Yamato ClockNAVI Body Fat Monitor, DF311

Regulation Number: 21 CFR §870.2770

Regulation Name: Impedance plethysmograph

Regulatory Class: II

Product Code: 74 MNW

Dated: November 18, 2002

Received: November 26, 2002

Dear Mr. Anselmo:

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.

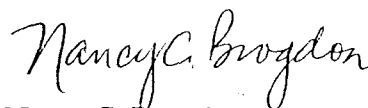
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K023942

Device Name: Yamato ClockMINI (DF301)
Yamato ClockNAVI (DF311)

Indications for Use:

The Yamato ClockMINI and ClockNAVI Body Fat Monitors are intended for use in the estimation of body fat percent in users between the ages of 10 and 80 years old.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Saperstein

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023942

Over-the-Counter Use

(Optional Format 3-10-98)