MAR 1 0 2003

SECTION 16 510(K) SUMMARY

1. DATE PREPARED

November 25, 2002

2. SPONSOR INFORMATION

Zewa Inc.
Mr. Thomas Zeindler
10438 N.W. 31st Terrace
Miami, Florida 33172

(305) 463-7551 (telephone)
(305) 463-7553 (facsimile)

3. DEVICE NAME

Proprietary Name:	Delwa-Star® WS-FM Blood Pressure and Body Fat Monitor
Common/Usual Name:	WS-FM Blood Pressure and Body Fat Monitor
Classification Name:	System, Measurement, Blood Pressure, Non Invasive/Plethysmograph, impedance

4. DEVICE DESCRIPTION AND INTENDED USE

The Delwa-Star® WS-FM Blood Pressure and Body Fat Monitor is intended for use by adults with moderately active to inactive lifestyles for measuring the systolic and diastolic blood pressure, and pulse rate (heart rate) by using an inflated cuff which is wrapped around the wrist. The device is also intended to estimate body fat by bioelectrical impedance analysis.

5. PREDICATE DEVICE

It is substantially equivalent to the Omron Body Fat Analyzer Model HBF-306 cleared by FDA on November 7, 2001 under 510(k) 011652 and the WS-500 Noninvasive Blood Pressure Measurement System cleared by FDA on March 5, 1999, under 510(k) K003444.

6. TECHNOLOGICAL CHARACTERISTICS

The Delwa-Star® WS-FM Blood Pressure and Body Fat Monitor uses bioelectrical impedance analysis, a well established technique, for body fat assessment. It measures the systolic and diastolic blood pressure, and pulse rate (heart rate) by use of an inflatable cuff that is wrapped around the wrist, a LCD display, a semiconductor sensor, and internal air pump, a battery power source and keys for operation.

7. DEVICE TESTING

The Delwa-Star® WS-FM Blood Pressure and Body Fat Monitor was tested for compliance with numerous technical specifications, including general performance under certain environmental conditions, influences of static electrical discharges, influences of irradiated electromagnetic field, and radio screening.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 0 2003

Mr. Thomas Zeindler
Vice President
Zewa Inc.
10438 N.W. 31st Terrace
MIAMI FL 33172

Re: K024077
Trade/Device Name: Delwa-Star® WS-FM Blood Pressure and Body Fat Monitor
Regulation Number: 21 CFR §870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: II
Product Code: 74 DXN
Regulation Number: 21 CFR §870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: 74 MNW
Dated: December 9, 2002
Received: December 10, 2002

Dear Mr. Zeindler:

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
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): Not assigned yet

Device Name: Trade Name: Delwa-Star® WS-FM Blood Pressure and Body Fat Monitor

Indications for Use: The Delwa-Star® WS-FM Blood Pressure and Body Fat Monitor is intended for use by adults with moderately active to inactive lifestyles for measuring the systolic and diastolic blood pressure, and pulse rate (heart rate) by using an inflated cuff which is wrapped around the wrist. The device is also intended to estimate body fat by bioelectrical impedance analysis.

Over-The-Counter Use.

PLEASE DO NOT WRITE BELOW THIS LINE
(Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K024077

Prescription Use _____ or Over-The-Counter Use ✓
(Per 21 CFR 801.109)