K062068
Pg 1 of 2

OCT 27 2006

510(k) SUMMARY

INTELWAVE HEART RATE VARIABILITY SYSTEM

1. Submitter Information

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of Section 513(i)(3) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. 807.92.

The submitter of this premarket notification is:
Alexander Riftine, Ph.D.
President
Intelwave, LLC
1090 King Georges Post Road Suite 1004
Edison, NJ 08837
Tel: (732) 738 – 8800
Fax: (732) 738 – 8877

This summary was prepared on June 07, 2006.

2. Name of device.

The name of the device is the Intelwave Heart Rate Variability System. The common name is the ECG monitor Heart Rate Variability System. The classification name is Electrocardiograph. 21 C.F.R. 870.2340.

3. Predicate device.

Intelwave 1.0 system is substantially equivalent to the following predicate devices:

1. Anscore™ Health Management System (510(k) K010955).
2. Holter Plus™ Ambulatory ECG Analysis System (510(k) K042463).
3. ANX 3.0 Respiratory and cardiac spectral frequency signal (510(k) K941252).
4. HeRO™ HRV analysis system (510(k) K021230).

K062068
pg 2 of 2

4. Device Description:

The Intelwave 1.0 System is a computer-based system for measurement of Heart Rate Variability (HRV) in response to paced respiration and controlled exercises.

The system performs a fully automated quantitative analysis of HRV based on data collected by an FDA-compliant R Wave Trigger device recommended or supplied by Intelwave. The system presents the results to the physician through a computer-based user interface. The system has patient data management capability.

5. Technological characteristics.

The measurement technology and the method of Heart Rate Variability analysis are essentially the same as those of the other legally marketed predicate devices.

6. Intended use:

The Intelwave 1.0 System is intended for use in heart rate variability (HRV) measurements in response to paced respiration and controlled exercises.

7. Performance data.

This product is designed to comply with ANSI/AAMI EC57: 1998/(R) 2003 "Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms". Performance testing of the Intelwave system included:

1) Comparison Performance Evaluation. Testing against the Holter Plus ™ system.

2) Validation of reliability of HRV assessment by the Intelwave system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 2006

IntelWave, LLC
c/o Alexander Riftine, PhD
1090 King Georges Post Rd Ste 1004
Edison, NJ, 08837

Re: K062068
Intelwave Heart Rate Variability System, Version 1.0
Regulation Number: 21 CFR 870.2340
Regulation Name: Electocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: October 4, 2006
Received: September 29, 2006

Dear Dr. Riftine:

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 Office of Compliance at (240) 276-0120. 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 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,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062068

Device Name: Intelwave 1.0

Indications For Use: The Intelwave 1.0 System is intended for use in Heart Rate Variability (HRV) measurements in response to paced respiration and controlled exercises.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062068