K070985

OSYPKA MEDICAL
Berlin, Germany • San Diego, California, USA

FEB - 1 2008

510(k) Summary

Date:	1 April 2007
Submitter:	Osypka Medical, Inc. 7855 Ivanhoe Avenue, Suite 226, La Jolla, CA 92037
Contact Person:	Markus Osypka, Ph.D., President Osypka Medical, Inc. 7855 Ivanhoe Avenue, Suite 226, La Jolla, California 92037 Phone: (858) 454 0021 Fax: (858) 454 0064
Device Trade Names:	CARDIOTRONIC™ AESCULON® AESCULON® CHF Clinic™ AESCULON® Hypertension Clinic™ AESCULON® Pacemaker Clinic™ OSYPKA MEDICAL® AESCULON® AESCULON® CHF Clinic™ AESCULON® Hypertension Clinic™ AESCULON® Pacemaker Clinic™
Common / Usual Names:	Hemodynamic Monitor, Cardiac Output Monitor, Cardiovascular Monitor
Classification Names:	21 CFR 870.2770 Impedance Plethysmograph
Regulatory Class:	Class II
Product Code:	DSB
Predicate Devices:	K011439 Cardiodynamics BIOZ.COM® Hemodynamic Monitor K033296 Masimo SET® Rad 5 Pulse Oximeter

<table>
<tr><td></td><td colspan="2">Both the AESCULON® and BIOZ.COM derive from the measurement of TEB
▪ the base impedance Z_0,
▪ the magnitude of the maximum rate of change of impedance $\left|\left(\frac{dZ(t)}{dt}\right)_{MIN}\right|$, and
▪ the left-ventricular flow time FT.</td></tr>
<tr><td rowspan="3">Theory / SV Algorithm</td><td colspan="2">The AESCULON differs from the predicate device BIOZ.COM® with respect to the theoretical interpretation of the measurements, in particular of the magnitude of the maximum rate of change of impedance $\left|\left(\frac{dZ(t)}{dt}\right)_{MIN}\right|$:</td></tr>
<tr><td>BIOZ.COM® (Predicate Device)</td><td>AESCULON®</td></tr>
<tr><td>ZMARC®

The interpretation of $\left|\left(\frac{dZ(t)}{dt}\right)_{MIN}\right|$ is that it is related to peak blood velocity. The BioZ.COM® derives thereof a velocity index (VI).

The BIOZ.COM® calculates the magnitude of the maximum of the second derivative of the change of impedance $\left|\left(\frac{d^2Z(t)}{dt^2}\right)_{MIN}\right|$ and derives thereof an acceleration index (ACI).</td><td>Electrical Velocimetry™

The interpretation of $\left|\left(\frac{dZ(t)}{dt}\right)_{MIN}\right|$ is that it is related to peak aortic blood acceleration. The AESCULON® derives thereof an index of contractility (ICON™).

Because the magnitude of the maximum rate of change of impedance $\left|\left(\frac{dZ(t)}{dt}\right)_{MIN}\right|$ is interpreted as being related to acceleration, no additional index is derived.</td></tr>
</table>

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Markus J. Osypka, Ph.D.
President
Osypka Medical, Inc.
7855 Ivanhoe Avenue, Suite 226
La Jolla, CA 92037

Re: K070985
Trade/Device Name: CARDIOTRONIC™ AESCULON®
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: Class II (two)
Product Code: DSB
Dated: January 20, 2007
Received: January 23, 2007

Dear Dr. Osypka:

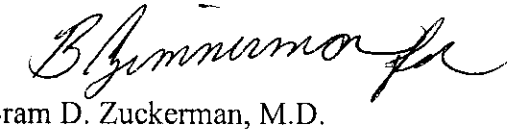
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (240) 276-0120. 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,



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): K070985

Device Name: AESCULON®
AESCULON® CHF Clinic™
AESCULON® Hypertension Clinic™
AESCULON® Pacemaker Clinic™

Indications for Use:

The AESCULON®, AESCULON® CHF Clinic™, AESCULON® Hypertension Clinic™ and AESCULON® Pacemaker Clinic™ are intended for noninvasive continuous monitoring of hemodynamic parameters for adult, pediatric, and neonatal patients in hospitals, hospital-type facilities, mobile, and home environments.

Prescription Use ✓ AND / OR Over-The-Counter-Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

B Hammerman

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K070985