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Section 5: 510(k) Summary

Category	Comments
Sponsor:	Therapeutic Monitoring Systems (TMS), Inc. 1900 Merivale Road, Suite 210, Ottawa, ON K2G 4N4 Canada Tel +1 613.368.4311 x403 Fax +1 613.368.4313 Company Contact: Simon P. Goulet, Chief Operating Officer sgoulet@therapeuticmonitoring.com
Correspondent Contact Information:	Craig Coombs Coombs Medical Device Consulting 1193 Sherman Street Alameda, CA 94501 Tel: 510-337-0140 Fax: 510-337-0416
Device Common Name:	Arrhythmia detector and alarm (including ST-segment measurement and alarm).
Device Classification Regulation & Name:	21CFR870.1025 monitor, physiological, patient (with arrhythmia detection or alarms)
Device Classification & Product Code:	Class 2, MHX
Device Proprietary Name:	CIMVA Universal
Category	Cardiovascular

Predicate Device Information:

Predicate Device:	IntelliVue
Predicate Device Manufacturer:	Philips
Predicate Device Common Name:	Arrhythmia detector and alarm (including ST-segment measurement and alarm).
Predicate Device Premarket Notification #	K103646
Predicate Device Classification:	21CFR870.1025
Predicate Device Classification & Product Code:	Class 2, MHX

b. Date Summary Prepared
1 March 2013

c. Description of Device
The CIMVA Universal software is resident in a hospital server or other computer that is periodically connected to a repository of recorded data from third party physiological monitors. The current version of the software has four functions:

1. Allows the user to import a specified amount of recorded monitor data (e.g. up to 96 hours) stored in external repositories.

2. Allows the physician to choose the type of multi-organ variability analysis that he/she desires.

3. Calculates the selected measures of Variability.

4. Provides a physician-configurable report of the calculations

CIMVA Universal also allows the clinician to measure the degree to which multi-organ variability measures are altered in response to clinical events that are input by the user.

The calculations performed by CIMVA Universal are algorithms available in the public domain (as described in journal articles, etc.). None of the variability measures are proprietary to TMS. The results of these analyses could help physicians conduct research on the potential clinical utility of one or more of these variability measurements.

d. Indications for Use

CIMVA Universal is indicated for analyzing patterns of variation of physiological parameters (heart rate and respiratory rate) derived from the output of third party monitoring systems. CIMVA Universal is not designed for vital signs monitoring or self-monitoring of patients.

e. Comparison to Predicate Device
The CIMVA Universal is not a stand-alone analysis device, rather it is intended to be an adjunct to third party physiological monitors. As a result, substantial equivalence is justified by comparing a third party physiological monitor (in this case the Philips IntelliVue; K103646) versus the same IntelliVue device with the CIMVA Universal attached.

The use of the CIMVA Universal does not change the intended use of the predicate device. The CIMVA Universal does not raise new or additional questions of safety or effectiveness because all analyses are retrospective and none of them constitute a vital sign. The CIMVA Universal has no alarms associated with its analysis.

The testing described below establishes that CIMVA Universal is in compliance with the Special Controls for Physiological Monitors with the product code MHX.

The company concludes that the Philips IntelliVue with the CIMVA Universal is substantially equivalent to the predicate Philips IntelliVue.

f. Summary of Supporting Data

Software validation has demonstrated that the CIMVA Universal is in compliance with the FDA's *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, and the applicable sections of the *Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm.*

Testing has demonstrated that the software device operates in accordance with its labeling claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 5, 2013

Therapeutic Monitoring Systems, Inc.
c/o Mr. Craig J. Coombs
President
Coombs Medical Device Consulting, Inc.
1193 Sherman Street
Alameda, CA 94501

Re: K123472
Trade/Device Name: CIMVA Universal
Regulatory Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (with arrhythmia detection or alarms)
Regulatory Class: II (two)
Product Code: 74 MHX
Dated: January 15, 2013
Received: January 16, 2013

Dear Mr. Coombs:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

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

Enclosure

K123472

Section 4: Indications for Use Statement

510(k) Number (if known): K123472

Device Name: CIMVA Universal

Indications For Use:

CIMVA Universal is indicated for analyzing patterns of variation of physiological parameters (heart rate and respiratory rate) derived from the output of third party monitoring systems. CIMVA Universal is not designed for vital signs monitoring or self-monitoring of patients.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Owen P. Faris -S