K112282 P1/2

NOV - 4 2011

mVisum, Inc.

Bringing Mobility to Healthcare

510(k) SUMMARY:

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92(c).

Submitter:

mVisum, Inc.
200 Federal Street, Suite 230
Camden, NJ 08103

Contact Person:

Praveen Dala
President and CEO
Phone: 856-513-0732
Fax: 856-513-0729

Date

August 05, 2011

Trade Name:

mVisum Alert Alarm Management System

Common/Usual Name:

Physiological Monitor System, Network and Communication (Patient Information Paging System)

Classification (if known):

Device Panel	Classification	Prod. Code	Description
Cardiovascular Devices	§870.2300 Class II	MSX	Cardiac Monitor (including cardiotachometer and rate alarm)

Predicate Devices:

mVisum Alert Alarm Management System is substantially equivalent to previously cleared GE / Data Critical Corporation Statview System pursuant to K990378 and GE Web Viewer, Pocket Viewer, Cellular Viewer pursuant to K061994.

Device Description:

The mVisum Alert Alarm Management System is a software based secondary alarm notification system that transmits alarms, text and physiological waveform data from patient monitoring devices to a graphical display. This could be either on a PC or on a mobile device carried by a trained professional in a hospital environment. It is also capable of transmitting alarms and physiological

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waveforms to clinician smartphones that operate on the cell phone data network. The system receives alarm conditions from patient monitoring networks through industry standard HL-7 or XML formats and transmits the notification including any waveform data to the client software component. The client software component can then display the text and the physiological waveform information to the clinician.

The mVisum system only reads alarm information and does not change it or modify it in any way. It does not diagnose alarms but transmits what the Patient Monitoring System determines to be an alarm.

Intended Use:

The mVisum Alert Alarm Management System is software intended for use to display status and alarm events from other medical devices and patient information systems and associated physiological and other patient information. It serves as a parallel, redundant mechanism to inform the clinical staff of patient events. It is intended to be a secondary means of annunciating and displaying patient alarm and physiological information to mobile healthcare providers.

The mVisum Alert is limited to use by qualified medical professionals who have been trained on the use of the system. It is intended to supplement and not to replace any part of the current patient monitoring systems. It is not considered in and of itself to be diagnostic without skilled interpretation and does not replace physician's care.

Predicate Devices

The product has the same technological characteristics as the legally marketed predicate devices. The mVisum Alert Alarm Management System and the predicate devices serve as secondary means of annunciating patient events and relaying information from the primary monitoring station through the use of a graphical user interface on a mobile device. The product has the same safety and efficacy characteristics as the predicate devices.

Testing

Verification, validation, and testing activities establish the performance, functionality, and safety of the system. Testing included system level and regression tests as well as tests driven by the Hazard Analysis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

NOV - 4 2011

mVisum, Inc.
c/o Mr. Praveen Dala, Ph.D.
President and CEO
200 Federal Street, Suite 230
Camden, NJ 08103

Re: K112282
Trade/Device Name: mVisum Alert Alarm Management System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Codes: MSX
Dated: August 5, 2011
Received: August 9, 2011

Dear Mr. Dala:

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.

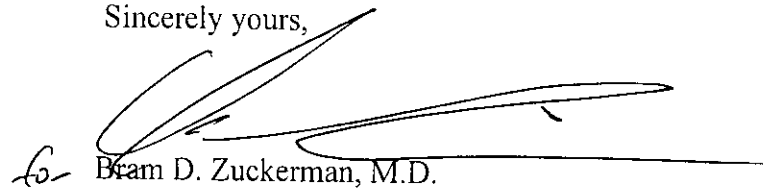
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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,



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

Enclosure

K112282

Indications for Use

510(k) Number (if known): K112282

Device Name: mVisum Alert Alarm Management System

Indications for Use:

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Prescription Use _√__ 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 K112282

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