

SECTION 5 - 510(K) SUMMARY

The following table provides background information regarding this Special 510(k) submission:

Date Prepared:	December 2, 2013
Submission Type:	Special 510(k): Device Modification
Device Trade Name:	NUVANT MCT System
Device Model Number:	MCTX-SY-nnn
Device Common Name:	Mobile Cardiac Telemetry (MCT)
Classification Regulation Name:	Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Product Code	DSI
Classification Regulation	21 CFR 870.1025
510(k) Submitter/Owner Name:	Corventis, Inc.
Submitter Address:	1410 Energy Park Drive, Suite 1 St. Paul, MN 55108
Contact Person:	Cheryl Swanson Director, Quality and Regulatory Affairs 1410 Energy Park Drive, Suite 1 St. Paul, MN 55108 (651) 925-3803 (office) (651) 762-1824 (cell) (551) 389-3251 (fax)
Predicate Device:	NUVANT Mobile Cardiac Telemetry System, cleared by FDA under 510(k) number K113372 on March 7, 2012.
Prior Submissions for this Change:	None

5.1 DEVICE DESCRIPTION

Please note that the only changes in the Device Description relate to replacing the patient trigger magnet with a button.

The NUVANT MCT System consists primarily of the PiiX monitoring device and the zLink data transmission device. Once activated, the wearable PiiX sensor continuously monitors the heart and automatically collects ECGs. When rhythm abnormalities are detected, data are automatically transmitted from the PiiX device to the zLink, which then automatically transmits the data to the Corventis Monitoring Center. Patients can also trigger transmission of ECGs when they experience cardiac symptoms by using the Patient Trigger Button. Certified cardiographic technicians at the Corventis Monitoring Center review received data and document symptoms reported by patients. Clinical reports, prepared by the Corventis Monitoring Center, are delivered and made available at www.corventis.com to provide data to prescribing physicians for the diagnosis and identification of various clinical conditions, events and/or trends.

5.1.1 HOW THE NUVANT MCT SYSTEM FUNCTIONS

Please note this is identical to the predicate NUVANT MCT System.

Once activated, the wearable PiiX sensor continuously monitors the heart and automatically transmits ECGs when rhythm abnormalities are detected.

Communication between the PiiX and zLink is enabled via BlueTooth™ technology, and communication between the zLink and the secure Corventis server is enabled via cellular technology.

5.1.2 SCIENTIFIC CONCEPTS OF THE DEVICE

The subject NUVANT MCT System uses proprietary algorithms based on rate, rhythm and morphology to continuously analyze rhythm abnormalities and to initiate automatic ECG transmission to the Server.

5.1.3 SIGNIFICANT PHYSICAL AND PERFORMANCE CHARACTERISTICS OF THE DEVICE

The subject NUVANT MCT System is comprised of the following non-sterile components:

- PiiX
- zLink
- Server

Please note these have always been cleared as a System, most recently under K113372.

PIIX

The PiiX is a patient-worn device applied to the patient's torso. It contains the electrode assembly and electronics module for recording ECG and heart rate data. The primary battery is contained in the electrode assembly and is a non-rechargeable Lithium Manganese Dioxide Thin Cell. The electronics module has a small 3V Manganese Silicon Lithium Rechargeable battery to maintain the Real Time Clock of the electronics module.

The electrode assembly (skin contacting portion) contains the following components that directly contact patient skin:

- Medical Grade Hydrogel Adhesive
- Medical Grade Clear Polyurethane Tape

The PiiX device lasts 7.5 days, and each package can contain up to four PiiX devices for up to 30 days of uninterrupted wear, depending on prescription length.

The entire electrode assembly meets requirements of the ISO 10993 biocompatibility standard.

ZLINK

Please note there are no changes to the zLink in this submission.

The zLink is the patient hand-held transceiver that receives information from the PiiX and transmits it to the Corventis Server. It also interacts with the Corventis Server to receive system configuration data and other relevant hardware diagnostic information.

The zLink components are surrounded by a plastic housing and the zLink contains a rechargeable Lithium Ion battery.

SERVER

The Server receives information from the PiiX via the zLink. The secure server, among other things, derives, calculates and displays the patient's physiological parameters using the data collected by the PiiX.

5.2 INTENDED USE OF THE DEVICE

Please note that the Intended Use of the Device is identical to the Predicate NUVANT MCT System.

The NUVANT MCT System is intended for the ambulatory recording and monitoring of physiological parameter(s).

5.3 INDICATIONS FOR USE STATEMENT

Please note that the Indications for Use are identical to the predicate NUVANT MCT System.

The NUVANT Mobile Cardiac Telemetry (MCT) System is intended to continuously measure, record and periodically transmit physiological data. The System is indicated for those patients who require monitoring for the detection of non-lethal cardiac arrhythmias such as, but not limited to, supraventricular tachycardias (e.g. atrial fibrillation, atrial flutter, paroxysmal SVTs), ventricular ectopy, bradyarrhythmias and conduction disorders. The NUVANT System monitors, derives and displays:

- ECG
- Heart Rate

5.4 TECHNOLOGICAL CHARACTERISTICS OF THE SUBJECT NUVANT MCT

The subject NUVANT MCT System operates identically to the predicate, based on the following fundamental scientific technology:

- The collection of physiological parameters by a multi-sensor patient-worn device (PiiX);
- The transmission of these parameters to a remote Server through a transceiver (zLink); and
- The receipt of the parameters by the Server and subsequent derivation into appropriate useful values for display.

This fundamental scientific technology is identical to the predicate NUVANT MCT System.

The only differences are non-fundamental to the scientific technology, as explained below:

1. Increase memory capacity of the PiiX to allow for continuous ECG recording and storage in device memory
2. Convert the PiiX into two parts consisting of an electrode assembly and an electronics module that can only be disassembled in the factory setting
3. Replace the patient trigger magnet with a push button on the PiiX

These proposed changes will not impact the fundamental scientific technology of the device. The subject NUVANT MCT system uses the same sensors, in the same scientific methods (algorithms for detection and transmission methods), as the predicate NUVANT MCT System.

5.5 SUMMARY OF TESTING

All of the proposed changes to the subject NUVANT MCT System were fully verified and validated in accordance with design control requirements.

5.5.1 SUMMARY OF TESTS USED TO DEMONSTRATE SUBSTANTIAL EQUIVALENCE

The Subject NUVANT MCT System is supported by the following tests to demonstrate substantial equivalence. Note that the zLink is unchanged in this submission, but was used in system validation tests and is further supported by the same tests as the Predicate NUVANT MCT System.

PiiX Verification and Validation Testing

- Biocompatibility Testing
- Mechanical Verification Testing
- Electrical Verification Testing
- Firmware Verification Testing
- System Validation Testing

Server Verification and Validation Tests

- Software Verification Testing
- System Validation Testing

5.5.2 GUIDANCE DOCUMENTS USED / CONSIDERED IN THESE DEVICE MODIFICATIONS

Guidance documents used/considered for these device modifications include, but are not limited to, the following:

- Draft Guidance Document titled *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*, issued June 14, 2013
- Draft Guidance Document titled *Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*, issued on April 23, 2013
- Draft Guidance Document titled *Design Considerations for Devices Intended for Home Use*, issued December 12, 2012
- *Radio Frequency Wireless Technology in Medical Devices*, issued on August 14, 2013
- *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, issued May 11, 2005
- *Class II Special Controls Guidance Document, Arrhythmia Detector and Alarm*, issued on October 28, 2003.

5.5.3 STANDARDS USED TO DEMONSTRATE SUBSTANTIAL EQUIVALENCE

The following standards were also used, in whole or in part, to demonstrate substantial equivalence:

Standards No.	Standards Title	FDA Recognition No.
IEC 60601-1	Medical electrical equipment - Part 1: General Requirements for Basic Safety and Essential Performance, 2006/A11:2011	5-4
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3), 2007	5-53
ANSI/AAMI/IEC 60601-2-47:2012	Medical electrical equipment - Part 2-47: Particular requirements for the safety and essential performance of ambulatory electrocardiographic systems	This standard replaces EC38 (FDA recognition number 3-65)
AAMI/ANSI/IEC 62304:2006	Medical Device Software – Software life cycle processes	13-32
AAMI/ANSI EC12	Disposable ECG electrodes, 2000(R) 2010	3-52

Standards No.	Standards Title	FDA Recognition No.
AAMI/ANSI EC57	Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms, 1998/(R) 2008	3-73
AAMI/ANSI/ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2-156
AAMI/ANSI/ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	2-153
AAMI/ANSI/ISO 10993-10:2010	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization	2-174

The results of the testing indicate that the subject NUVANT MCT System performs as intended. Risk analysis and testing further confirmed that the changes did not introduce any new issues of safety or effectiveness, and the system performs as well as the predicate device.

5.6 CONCLUSION

The Indications for Use for the subject NUVANT MCT System are identical to our previous device (K113372). We have provided summary data to demonstrate reasonable assurance of the safety and effectiveness of the subject NUVANT MCT System and to demonstrate substantial equivalence to its predicate.

As supported by the descriptive information, verification, validation and standards testing, the modified NUVANT MCT System is as safe and effective, and performs as well as or better than the predicate device.

Therefore, the NUVANT MCT System is substantially equivalent to the legally marketed predicate device.



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

February 6, 2014

Corventis, Inc
Cheryl Swanson
Director, Quality and Regulatory Affairs
1410 Energy Park Drive, Suite 1
St. Paul, MN 55108

Re: K133701
Trade/Device Name: NUVANT MCT System
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (Including ST-Segment
Measurement and Alarm)
Regulatory Class: Class II
Product Code: DSI
Dated: January 7, 2014
Received: January 8, 2014

Dear Cheryl Swanson:

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 contact 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

SECTION 4 - INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): N/A

Device Name: NUVANT® Mobile Cardiac Telemetry System

Indications for Use:

The NUVANT Mobile Cardiac Telemetry (MCT) System is intended to continuously measure, record and periodically transmit physiological data. The System is indicated for those patients who require monitoring for the detection of non-lethal cardiac arrhythmias such as, but not limited to, supraventricular tachycardias (e.g. atrial fibrillation, atrial flutter, paroxysmal SVTs), ventricular ectopy, bradyarrhythmias and conduction disorders. The NUVANT System monitors, derives and displays:

- ECG
- Heart Rate

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

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OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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