DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 21, 2016

Medicomp, Inc.
% Susan Goldstein-Falk
Official Correspondent
Mdi Consultants
55 Northern Blvd
Great Neck, New York 11021

Re: K161916
Trade/Device Name: TelePatch Cardiac Monitor PM750
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter And Receiver
Regulatory Class: Class II
Product Code: DRG, MLO
Dated: November 8, 2016
Received: November 10, 2016

Dear Susan Goldstein-Falk:

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.

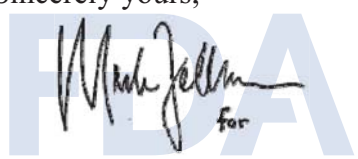
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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



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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161916

Device Name
TelePatch Cardiac Monitor PM750

Indications for Use *(Describe)*

The TelePatch Cardiac Monitor PM750, is a pager-sized, handheld or patient worn device designed specifically to record and transmit ambulatory ECG signals. The device is designated as Rx only, to be worn by infants to adults of all ages. The device can be worn for days or weeks, as it is intended for use by patients who are experiencing symptoms that are transient and infrequent in nature.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

The assigned 5l0(k) number is **K161916**

1. Submitter's Identification:

Medicomp, Inc.
600 Atlantis Rd.
Melbourne FL 32941

Contact: Mr. Sean A. Marcus
Tel: 321-676-0100 ext.2150

Date Summary Prepared: **December 12, 2016**

2. Name of the Device:

TelePatch Cardiac Monitor PM750

3. Common or Usual Name:

Transmitters and Receivers, Physiological Signal, Radiofrequency

Regulation Number**:** 21 CFR Part 870.2910
Regulation Name: Transmitters and Receivers, Physiological Signal, Radiofrequency
Regulatory Class: II
Product Code: DRG

Electrocardiograph, Ambulatory with Analysis Algorithm

Regulation Number: 21 CFR Part 870.2800
Regulation Name: Electrocardiograph Ambulatory, with Analysis Algorithm
Regulatory Class: II
Product Code: MLO

4. Predicate Device Information:

K#043454, CardioPAL SAVI (Model PM410) Event /Loop Recorder, Medicomp Inc., K#091696, SAVI Wireless (Model PM500) Radiofrequency Physiological Signal Transmitter and Receiver, Medicomp, Inc.

5. Device Description:

TelePatch Cardiac Monitor PM750 is a small, auto triggered, device, prescribed by physicians for patients who are experiencing symptoms that may be attributable to cardiac arrhythmia. Shortness of breath and palpations are examples of these symptoms. This device may be worn for a period of days or weeks - whatever time is necessary to capture and record the ECG.

The PM750 has two operating modes to allow for event analysis of the recorded ECG or in Holter mode to allow for full disclosure analysis of the recorded ECG.

The device is comprised of the function contained within the CardioPAL SAVI (Model PM410) ECG loop recorder and the SAVI Wireless (Model PM500) event monitor and an off the shelf cellular phone. The device can be used with a break-away lanyard and has interaction with a PC interface cable.

6. Indications for Use:

The TelePatch Cardiac Monitor PM750, is a pager-sized, handheld or patient worn device designed specifically to record and transmit ambulatory ECG signals. The device is designated as Rx only, to be worn by infants to adults of all ages. The device can be worn for days or weeks, as it is intended for use by patients who are experiencing symptoms that are transient and infrequent in nature.

7. Comparison to Predicate Device (Substantial Equivalence):

The following comparison chart outlines similarities and differences between the subject and the predicate device:

Features	**Predicate Device** CardioPAL SAVI (PM410) K#043454	**Predicate Device** SAVI Wireless (PM500) K#091696	**Subject Device** TelePatch Cardiac Monitor (PM750)	**Substantially Equivalent or Different**
ECG Storage	20 Minutes	30 Days	30 Days	SE
On Board Analysis	Yes	Yes	Yes	SE
ECG Input	1 Channel 2 Wires 1 Channel 3 Wires 2 Channel 3 Wires 2 Channel 5 Wires	1 Channel 2 Wires 1 Channel 3 Wires 2 Channel 3 Wires 2 Channel 5 Wires	1 Channel 3 Wires 1 Channel 5 Wires 2 Channel 3 Wires 2 Channel 5 Wires 1 Channel Electrode Patch 2 Channel Electrode Patch	SE
User Interface	Audio Beeper 2 line x 16 Character LCD 3 buttons	Audio Beeper 2 Buttons Cellular Telephone	Audio Beeper 2 Buttons Cellular Telephone	SE
PC Interface	Trans-telephonic USB	Cellular Network Bluetooth USB	Cellular Network Bluetooth USB	SE
Case	Plastic	Plastic	Plastic	SE
EC38 Type	Type 3	Type 3	Type 3	SE
Battery	1 AA 1 Coin cell	1 AA	1 Coin cell 1 Lithium Ion	SE
Operating & Storage Humidity	10% to 95%, non-condensing	10% to 95%, non-condensing	10% to 95%, non-condensing	SE
Operating Temperature	0°C to 45°C (32° F to 113° F)	0°C to 40°C (32° F to 104° F)	0°C to 45°C (32°F to 113°F)	SE
Storage Temperature	-20°C to 65° C (-4° F to 149° F)	-20°C to 65°C (-4° F to 149° F)	-15°C to 60°C (-5°F to 140°F)	SE
Atmospheric Pressure: Operating	N/A	N/A	700 hPa to 1060 hPa	SE

Atmospheric Pressure: Storage/Transport	N/A	N/A	N/A	SE
Shipment Temperature	N/A	N/A	-15°C to 60°C (-5°F to 140°F)	SE
Indications For Use	The CardioPAL SAVI event monitor is a pager-sized, handheld or patient-worn device designed specifically to record and transmit ambulatory ECG signals. The device can be worn for days or weeks, as it is intended for use by patients who are experiencing symptoms that are transient and infrequent in nature.	The SAVI Wireless PM500 is a pager-sized, handheld or patient-worn device designed specifically to record and transmit ambulatory ECG signals. The device can be worn for days or weeks, as it is intended for use by patients who are experiencing symptoms that are transient and infrequent in nature.	The TelePatch Cardiac Monitor PM750, is a pager-sized, handheld or patient worn device designed specifically to record and transmit ambulatory ECG signals. The device is designated as Rx only, to be worn by infants to adults of all ages. The device can be worn for days or weeks, as it is intended for use by patients who are experiencing symptoms that are transient and infrequent in nature.	SE
Target Population	N/A	"System can be used for infants weighing less than 10kg"	IFU: "The device is designated as Rx only, to be worn by infants to adults of all ages." OVERVIEW: "The TelePatch System can be worn by users weighing less than 10kg."	SE
Prescription Designation	CAUTION NOTICE: "Federal law restricts the CardioPAL SAVI (PM410) to sale by, or on the order of, a licensed medical practitioner."	CAUTION NOTICE: "Federal law restricts the SAVI Wireless™ to sale by, or on the order of, a licensed medical practitioner."	COVER: "TelePatch is intended for use as prescribed by a physician who wants to follow cardiac activity." CAUTION NOTICE: "Federal law restricts the TelePatch Cardiac Monitor PM750 to sale by, or on the order of, a licensed medical practitioner." IFU: "The device is designated as Rx only, to be worn by infants to adults of all ages.	SE

Discussion of Similarities and Differences:

ECG output is unchanged. The technology for wire configurations is unchanged, using off-the-shelf industry standard electrodes for data input via wires as well as an electrode patch with flex circuit for data input.

The current user interface remains the same, using two buttons for user interaction. An off the shelf cellular phone, with graphic LCD, remains the same. The graphical LCD communicates device status to the user in text and graphical icons, as the device does currently. The audio beeper and LED interaction functions equivalently, to provide feedback to the user.

The interface is unchanged. ECG is transmitted via digital cellular network, a Bluetooth interface is used to send ECG to the cellular telephone and configure device parameters. The intent of the USB PC interface has not changed. The USB PC interface is used to download Holter procedures as well as configure device parameters including default options, and software download.

The case size has been changed accommodating deprecated parts, as indicated below. The composition of the case remains plastic.

The requirement of an EC38 type-3 device is unchanged.

Environmental conditions remain substantially equivalent to the predicate devices. Operating and Storage Humidity remains the same, the Operating Temperature in the subject device is safe and effective as the predicate devices. Storage Temperature remains substantially equivalent. Atmospheric Pressure in the predicate devices were not tested to IEC 60601-1-11 as this standard was introduced 4/1/2010. The subject device fell within the acceptable parameters of 700 hPa to 1060 hPa when tested for Atmospheric Pressure Operating conditions. There were no applicable shipment or Storage/Transport Atmospheric Pressure requirements specified for the predicate or subject devices.

The subject device Indications for Use Statement (IFU) has been updated to reflect target population, as suggested in the Premarket Assessment of Pediatric Medical Devices (3/24/14), pg.11, section A: Basic Elements of Labeling, Indications for Use. Additionally, the IFU states the prescription designation as noted in 21 CFR 801.109 (c).

Target population is now presented in the IFU. The acceptable minimum weight requirement of <10kg is the same as the predicate device and is substantiated by IEC 60601-2-47 requirements.

Rx designation has been noted in the User Manuals in both predicate and subject devices as required by 21 CFR 801.109 (1). The Rx designation has been added to the IFU per 21 CFR 801.109 (c).

Based on the aforementioned information, the subject device is substantially equivalent to the two predicate devices.

Testing information demonstrating safety and effectiveness of the subject PM750 device in the intended environment of use is supported by the following testing that was conducted with conformance to the following standards:

1) AAMI/ANSI/IEC 60601-1 Medical Electrical Equipment: General requirements for basic safety and essential performance. 19-4 2012

2) IEC 60601-1-2 Medical Electrical Equipment: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Disturbances-Requirements and Tests. 19-8 2014

3) IEC 60601-1-6: 2010 Medical Electrical Equipment: General Requirement for Safety and
Collateral Standard: Usability 5-85 20

4) IEC 60601-1-11 Medical Electrical Equipment: Home Healthcare Environment 19-14 2015

5) AAMI/ANSI/IEC 60601-2-47 Medical Electrical Equipment: Ambulatory Electrocardiographic Systems 3-128 2012

6) AAMI/ANSI/ISO 14971:2007 Medical Devices – Application of Risk Management to Medical Devices 5-70 2010

7) IEC 62366 Medical Devices – Application of Usability Engineering to Medical Devices
5-96 2015

8) AAMI/ANSI/ISO 10993-5 Biological Evaluation of Medical Devices- Part 5: Tests for In Vitro Cytotoxicity 2.153 2014

9) AAMI/ANSI/ISO 10993-10 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization 2-173 2010

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was our conclusion that the Medicomp Inc., TelePatch Cardiac Monitor PM750 testing meets all relevant requirements of the aforementioned tests.

8. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

All testing performed on the TelePatch Cardiac Monitor PM750 was derived from the risk assessment which evaluated the effects of the feature changes. Testing included AAMI/ANSI/IEC 60601-1, IEC 60601-1-2, IEC 60812, ISO 14971 and environmental and software validation testing.

9. Discussion of Clinical Tests Performed:

Not Applicable

10. Conclusions:

The subject device, TelePatch Cardiac Monitor PM750, has identical indications for use as the predicate devices: CardioPAL SAVI (PM410) and SAVI Wireless (PM500). The validation testing contained in our submission demonstrates that there are no differences in their technological characteristics, thereby not raising any new issues of safety or effectiveness. Thus, the TelePatch Cardiac Monitor PM750 is substantially equivalent to both predicate devices, the CardioPAL SAVI (PM410) and the SAVI Wireless (PM500).