K100217
p1/4

510(k) Summary of Safety and Effectiveness

Submitter

Mediana Co.,Ltd.
Dongwha Medical Instrument Complex, 1650-1, Donghwa-ri, Munmak-eup,
Wonju-si, Gangwon-do, Korea
Tel) +8270-7092-9983 Fax) +822-542-7447
Company Contact: Amy M.H.KIM, Manager of Regulatory Affairs
Won W.N.LEE, Specialist of Regulatory Affairs
Date Summary Prepared: November 2nd, 2009

JUN - 8 2010

Device Name

Trade Name: Lucon M-series (M20, M30) patient monitor
Common Name: Patient Monitor
Classification Name: Cardiac Monitor (21CFR870.2300) also contains
Monitor, Physiological, Patient (21CFR870.2300)
(including arrhythmia detection or alarms),
Arrhythmia Detector and alarm (21CFR870.1025)
(including ST-segment measurement and alarm),
NIBP measurement system (21CFR870.1130),
Electrocardiograph (21 CFR870.2340)
Non-invasive pulse oximetry, SpO2 (21CFR870.2700) and
Clinical electronic thermometer (21CFR870.2910)

Classification: Class II

Predicate Devices (Legally Marketed Devices)

The predicate devices for Vital signs monitors, Model Lucon M-series (M20, M30) are:

- **Omron Health care Co.,Ltd.** Vital Signs Monitors, Model HBP-2070 cleared by FDA through 510(k) No. **K082812**, and
- **Philips Medical Systems Co.,Ltd.** Patient Monitors, SureSigns VM6 series cleared by FDA through 510(k) No. **K080495**, and
- **Welch Allyn Protocol Inc.** Cardiac Monitors, Propaq Encore 200 series cleared by FDA through 510(k) No. **K012451**, and
- **Spacelabs Healthcare Inc.** Vital Signs Monitors, Model 91220 cleared by FDA through 510(k) No. **K062095**.

Device Description

The Mediana Lucon M-series (M20, M30) patient monitor is a lightweight and compact device (250 × 210 × 170 (mm) and 3.2 kg) powered by AC mains (100-240VAC, 50-60Hz) and also powered by internal battery. The monitor provides patient data and monitoring status on TFT-LCD displays.

- Electrocardiography (ECG)
- Heart rate (HR)
- Noninvasive blood pressure (NIBP)
- Functional arterial oxygen saturation (SpO2)
- Pulse rate (PR)
- Respiration rate (RR)
- Temperature (Temp)
- Arrhythmia/ST segment (M30 only)
- Capnography (M30 only)

Intended Use

The Lucon M-series (M20, M30) is intended to be used to monitor for adult, pediatric and neonatal patients in all areas of a hospital and hospital-type facilities. Monitor users should be skilled at the level of a technician. The device is capable of monitoring:

- Electrocardiography (ECG)
- Heart rate (HR)
- Noninvasive blood pressure (NIBP)
- Functional arterial oxygen saturation (SpO2)
- Pulse rate (PR)
- Respiration rate (RR)
- Temperature (Temp)
- Arrhythmia/ST segment (M30 only)
- Capnography (M30 only)

Note: Hospital use typically includes such areas as general care floors, operating rooms, special procedure areas, intensive and critical care area, within the hospital. Hospital type facilities include physician office-based facilities, sleep labs, skilled nursing facilities, surgical centers, and sub acute care centers.

Note: The medically skilled and trained user can be clinicians like doctors and nurses who know how to take and interpret a patient's vital signs. These clinicians must take direct responsibility for the patient's life. This can include care-givers or medically trained interpreters who are authorized under the appropriate clinical facility procedures to support patient care. Any inappropriate setting, especially the alarm limit or alarm notification settings, can lead to a hazardous situation that injures the patient, harms the patient, or threatens the patient's life. This equipment should only be operated by trained users who can adjust the settings of the patient monitor.

Summary of Technical Characteristics of the Device Compared to the Predicate Devices (Legally Marketed Devices)

The Mediana patient monitors, Model Lucon M-Series (M20, M30) are substantially equivalent to the HBP-2070 of Omron Healthcare(No. **K082812**), SureSigns VM6 series of Philips Medical Systems (No. **K080495**). and Propaq Encore Model 200 series of Welch Allyn Inc (No. **K012451**). and mCARE 300, Model 91220, Vital Signs Monitor of Spacelabs Medical(No. **K062095**).

- The Lucon M-series (M20, M30) monitors use the Mediana ECG module, MDE-1 which is identical to the module used in the HBP-2070. The **Electrocardiogram(ECG) and heart rate** specifications for the Lucon M-series (M20, M30) and HBP-2070 are identical. The ECG measurement performance in VM6 is similar to those in the Lucon M-series (M20, M30) monitors. Because those devices are used identical technology to measure the ECG parameter,

- The Lucon M-series (M20, M30) monitors use the Omron NIBP module M3200 which is identical to the module used in the HBP-2070. The **Non-invasive blood pressure (NIBP)** specifications for the Lucon M-series (M20, M30) and HBP-2070 are identical. And these devices and SureSigns VM6 series comply with the AAMI performance standard SP-10 & IEC60601-2-30 and have same technology to measure the NIBP parameter,

- The Lucon M-series (M20, M30) monitors use the Nellcor SpO2 module, NELL-3 which is used in the mCARE 300, 91220 and HBP-2070. The **Pulse Oximetry (SpO2)** specifications for the model Lucon M-series (M20, M30), HBP-2070 and 91220 are identical. Also, all devices comply with the performance standard ISO9919.

- The **Respiration** can be obtained from either the Electrocardiogram (ECG) channel or the Capnography (EtCO2) channel. The algorithm of **Impedance measurement** in HBP-2070 is identical to that in Lucon M-series (M20, M30) and the respiration specification for the Lucon M-series (M20, M30) and HBP-2070 are identical Because the respiration measurement (Thoracic Impedance) for HBP-2070 and 91220 are from ECG module that are the same module designed and manufactured by Mediana Co.,Ltd.,

- The Capnography (EtCO2) module is installed to Lucon M-series (M30 only), The algorithm of **Airway Measurement** in 91220 has identical performance of Lucon M-series (M30 only). Because Airway Measurement is from Capnography module which is manufactured by Philips Respironics Inc. The operation theory of Airway Measurement in Propaq Encore 200 series is same as those in Lucon M-series (M30 only) and 91220 for respiration measurement,

- The Lucon M-series (M20, M30) monitors use the thermometry MDT-1 module which is identical to used in HBP-2070 and 91220. The **Temperature** measurement technology is equivalent for the model Lucon M-series (M20, M30), HBP-2070 and 91220. Also YSI 400 and 700 probes/probe covers are used for all of these device,

- The **Pulse rate** derived from the non-invasive blood pressure (NIBP) channel is from M3200 NIBP module in Lucon M-series (M20, M30). Also, this M3200 module is used for HBP-2070 . And the pulse rate derived from the Pulse Oximetry (SpO2) channel is from NELL-3 SpO2 modules in Lucon M-series (M20, M30). Also, this NELL-3 module is used for HBP-2070 and 91220 too.

- The Lucon M-series (M30 only) monitors use the Capnostat 5 and Lo Flo C5 which have already been registered in FDA by Philips Respironics Inc. (#K042601 is for Capnostat 5, #K053174 is for Lo Flo C5). The **Capnography** measurement module in Lucon M-series (M30 only), is from Respironics Capnography module, both modules are identical to the modules used in the 91220. Also the difference of Propaq Encore 200 series in Capnography specification is minor between the identified predicate devices for all measurements. All 3 devices have identical technology and operation of theory for Capnography,

- The model Lucon M-series (M20, M30) monitors as well as the predicate devices have internal power source, a rechargeable lead acid battery and AC power.

Summary of Performance Testing

The Mediana vital signs monitors, Model Lucon M-series (M20, M30) substantially have been tested in accordance with the system V & V plan (#MDR-YW071202-02) and summary included with the submission using production equivalent units prior to release to market.

A risk analysis identifying potential hazards and documenting mitigation of the hazards has been developed and applied as part of Mediana design control procedure. Mediana's quality system confirms to 21CFR820, ISO 9001, ISO13485 and CMDCAS ISO 13485 certified by DNV (Det Norske Veritas).

Conclusions

As stated above, the Mediana patient monitors, Model Lucon M-Series (M30, M20) are safe and effective and comply with the appropriate medical device standards and are substantially equivalent to the earlier identified predicate devices.

- End of Section -

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

Mediana Co., Ltd.
c/o Mr. Charles Mack
Principal Engineer
International Regulatory Consultants, LLC
77325 Joyce Way
Echo, OR 97826

JUN - 8 2010

Re: K100217
Trade/Device Name: Lucon M-series (M20, M30) Patient Monitor
Regulatory Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (with arrhythmia detection or alarms)
Regulatory Class: II (two)
Product Code: MHX
Dated: May 15, 2010
Received: May 19, 2010

Dear Mr. Mack:

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

K100217

INDICATIONS FOR USE

Applicant:
Mediana Co.,Ltd.
Dongwha Medical Instrument Complex,
1650-1, Donghwa-ri, Munmak-eup,
Wonju-si, Gangwon-do, Korea
Telephone: (82) 70 7092 9983
Fax: (82) 33 742 5498

510(k) Number: _____

Device Name: Lucon M-series (M20,M30), patient monitor

Indications for Use:

The Lucon M-series (M20, M30) is intended to be used to monitor for adult, pediatric and neonatal patients in all areas of a hospital and hospital-type facilities. Monitor users should be skilled at the level of a technician. The device is capable of monitoring:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100217

Prescription Use X OR Over-The-Counter _____
(Per 21CFR801.109)

- End of Section -