Non-Confidential Summary of Safety and Effectiveness

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23-Sep-08

OCT 22 2008

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Official Contact: Ranndy Kellogg – VP Marketing & Product Development

Proprietary or Trade Name: HBP-2070

Common/Usual Name: Monitor, Physiological, Patient (without arrhythmia detection or alarms)

Classification Name/Code: DXN – System, Measurement, Blood-pressure, Non-invasive

Device: Model – HBP-2070

Predicate Devices: Omron – Press-Mate Advantage – K973637

Device Description:
The proposed vital signs monitor is a modification of a previously cleared Colin Press Mate Advantage (K973637).

The proposed model, HBP-2070, measures and monitors:
- Noninvasive blood pressure (NIBP)
- Oxygen saturation (SpO2)
- ECG
- Respiration rate (RR)
- Heart Rate (HR), and
- Temperature

Indications for Use:
The HBP-2070 is intended to be used to monitor electrocardiography (ECG), heart rate (HR), noninvasive blood pressure (systolic, diastolic and mean arterial pressure) (NIBP), functional arterial oxygen saturation (SpO2), pulse rate (PR), respiration (RR) temperature (Temp) 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, doctor, nurse, or medical specialist.
Patient Population: Adult, Pediatric, Neonate

Environment of Use: All areas of a hospital and hospital-type facilities

Contraindications: None

Summary of substantial equivalence

Indications for Use
Monitors:
- Non-invasive blood pressure (NIBP),
- Oxygen saturation (SpO2),
- ECG,
- Respiration rate,
- Heart rate (HR), and
- Body Temperature (Temp)

Summary of substantial equivalence

Indications for Use
Monitors:
- Non-invasive blood pressure (NIBP),
- Oxygen saturation (SpO2),
- ECG,
- Respiration rate,
- Heart rate (HR), and
- Body Temperature (Temp)

Environmental Condition

Operating conditions
- 0 to 40 °C,
- 30 to 85 %RH non-condensing

Storage conditions
- -20 to 70 °C,
- 10 to 100 %RH non-condensing

Display
- Screen size: 5.6inch TFT color LCD
- Resolution: 400 × 320 pixel
- Number of Traces: 1 or 2 waveforms

Electrical
- Power source: AC Mains
- Battery (lead acid)
- AC: 100-120V 50 / 60Hz
- Battery: 12V 1.8Ah
- Power range: A battery typically provides operating time of 30 minutes when fully charged with no printing, no external communication, no audible alarm sound and one NIBP measurement per 5 minutes at 25°C.

- Battery operation time: A battery typically provides operating time of 1 hour and 6 hour when fully charged with no printing, no external communication, no audible alarm sound and one NIBP measurement per 10 minutes at 25°C.
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Predicate
Press-Mate Advantage
K973637

New Model
HBP-2070 series

Recorder
Type
Resolution
Number of Channel
Paper width
Paper speed

Press-Mate Advantage
K973637

same as predicate device
same as predicate device
same as predicate device
50 mm
25 and 50mm/sec

Measurement method
Oscillometric method

Patient target
Adult, Pediatric, Neonatal

NIBP
SYS - Adult) 60 - 250 mmHg
MAP - Adult) 45 - 235 mmHg
PEDIATRIC / Neonatal) 40 - 120 mmHg

Measurement range

0-300mmHg ( Adult )
0-150mmHg(Neo)

Pressure display range

0-300 mmHg

Accuracy of pressure indicator
Within ±3 mmHg or 1 % of reading

Pressure sensor
Semiconductor pressure sensor

Accuracy of pulse rate
Within ±2 beats/min or ±2% of reading

Inflation method
DC Rolling diaphragm pump

Deflation method
Dynamic linear deflation

Shock protection
Type BF(Defibrillator protected)

ECG
Lead
3 / 5 Lead

Lead off detection
Detected and displayed

Input dynamic range
±5mV AC, ±300mV DC

Voltage range
±0.5mV ~ ±5mV

Signal Width
40 ms ~ 120 ms ( Q to S )

Frequency response
Low Extend
0.05 Hz - 40 Hz

Filter
None

Monitor
0.32 Hz - 40 Hz

Respiration rejection
None

ECG size
×1/2,×1,×2,×4

Display Sweep Size
6.25,12.5,25 mm/sec

Shock protection
Type CF(Defibrillator protected)

Omron HBP-2070
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**Premarket Notification 510(k) Omron HBP-2070**

**Section 5 – 510(k) Summary**

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### [RESP]

**Measurement method**
- Trans-thoracic impedance

**Range**
- 3 to 150 breaths/min

**Accuracy of pulse rate**
- ±3 breaths/min

**Lead**
- RA to LL

**Display Sweep Size**
- 6.25, 12.5, 25 mm/sec

**Shock protection**
- Type CF (Defibrillator protected)

### [SpO2]

**SpO2 module**
- Nellcor MP-203

**Measurement method**
- 2 wave length pulse wave type

**SpO2 display range**
- 50 - 100 %

**Accuracy**
- Adult - 70% - 100% ±2digits
- 1% - 69% unspecified
- Pediatric / Neonate
  - 70% - 100% ±3digits
  - 1% - 69% unspecified

**Display Sweep Size**
- 12.5, 25, 50 mm/sec

**Pulse rate display range**
- 20 - 250 beats/min

**Accuracy of pulse rate**
- Within ±3 beats/min

**Shock protection**
- Type BF (Defibrillator protected)

### [TEMP]

**Measurement method**
- Thermistor probe YSI 400 or 700

**Parameter Displayed**
- Temp ( 1 ch )

**display range**
- 15.0 - 45.0°C

**Accuracy**
- ±0.1°C (25°C to 45°C)
- ±0.2°C (15°C to less than 25°C)

**Scale**
- Selectable from C to F

**Probe Accuracy**
- ±0.1°C

**Shock protection**
- Type BF (Defibrillator protected)

The base modifications are:

- Change in the SpO2 module to Nell 3 which has been used and cleared in our predicate BPS S510 (K063690).
- Change in the NIBP module to M3500 which has been used in our predicate HBP- T105 (K071645).
- Software updates.
Differences Between Other Legally Marketed Predicate Devices

The Omron HBP-2070 vital signs monitor is viewed as substantially equivalent to the predicate device because:

**Indications** –
- Identical to predicate – K973637

**Technology** –
- Identical algorithms to predicate – K071645

**Materials** –
- The materials in patient contact are identical to predicate devices as listed in Section 15.

**Environment of Use** –
- Identical to predicate – K973637

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.
Dear Mr. Dryden:

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 such 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); 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health’s (CDRH’s) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH’s Office of Surveillance and Biometric’s (OSB’s) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

[Signature]

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

Enclosure
Indications for Use Statement

510(k) Number: \_K0828\_2 (To be assigned)

Device Name: HBP-2070

Indications for Use:

The HBP-2070 is intended to be used to monitor electrocardiography (ECG), heart rate (HR), noninvasive blood pressure (systolic, diastolic and mean arterial pressure) (NIBP), functional arterial oxygen saturation (SpO₂), pulse rate (PR), respiration (RR) temperature (Temp) 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, doctor, nurse, or medical specialist.

Prescription Use XX 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)

[Signature]

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number \_K0828\_2