August 16, 2018

Shenzhen Comen Medical Instruments Co., Ltd.
Hongbo Yan
Registration Engineer
South of Floor 7, Block 5 4th Industrial Area of Nanyou
Nanshan District
Shenzhen, 518052 CN

Re: K173454
Trade/Device Name: Multi-parameter Patient Monitor, Model C30
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II
Product Code: DRT, DPS, DSJ, DSK, DXN, DQA, DSB, FLL
Dated: July 23, 2018
Received: July 23, 2018

Dear Hongbo Yan:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica E. Paulsen -S

for

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173454

Device Name
Multi-parameter Patient Monitor, Model C30

Indications for Use *(Describe)*
C30 Multi-parameter Patient Monitor (hereinafter called Patient Monitor) is indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. It's used for monitoring, reviewing and storing of multiple physiological parameters as following: ECG, heart rate (HR), respiration (Resp), temperature (Temp), SpO2, pulse rate (PR), non-invasive blood pressure (NIBP) of single patient. All parameters can be applied to adult, pediatric or neonate. The Patient Monitor is not intended to be used on the patients with pacemaker.

The monitor is used for monitoring the clinical patients, so only the doctors and nurses who are qualified through training can use these monitors.

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.

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510 (k) Summary
C30 Multi-parameter Patient Monitor

This 510(k) Summary is provided in accordance with the requirements of 21 CER 807.92.

Date: Aug 14, 2018

Submitter: SHENZHEN COMEN MEDICAL INSTRUMENTS CO.,LTD

South of Floor 7, Block 5 4th Industrial Area of Nanyou, Nanshan District, Shenzhen, Guangdong, 518052, P.R.China

No.2 of FIYTA Timepiece Building, Nanhuan Avenue, Gongming Sub-district, Guangming New District, Shenzhen, Guangdong, 518106, P.R.China.

Contact: Hongbo Yan

Registration Engineer

Telephone: +86-13424152596

Facsimile: +86-755-26431232

Device Trade Name: Multi-parameter Patient Monitor, Model C30

Common Name: Multi-parameter Patient Monitor

Device Classification:

Device Panel	Classification	ProCode	Description
Cardiovascular Devices**:**	*§870.2300, II*	*DRT*	*Cardiac Monitor (incl. Rate Alarm)*
	§870.1110, II	*DSK*	*Computer, Blood Pressure*
	§870.1130, II	*DXN*	*System, Measurement, Blood-Pressure, Non-Invasive*
	§870.1100, II	*DSJ*	Alarm, Blood Pressure
	§870.2300, II	DRT	Monitor, Cardiac (incl. Cardiotachometer& Rate Alarm)
	§870.2340, II	DPS	Electrocardiograph

<table>
<tr><td></td><td>§870.2700, II</td><td>DQA</td><td>Oximeter</td></tr>
<tr><td></td><td>§870.2770, IT</td><td>DSB</td><td>Plethysmograph, Impedance</td></tr>
<tr><td>General Hospital</td><td>§880 .2910, II</td><td>FLL</td><td>Thermometer, Electronic, Clinical</td></tr>
<tr><td>Predicate Devices:</td><td colspan="3">K123074, BeneView T1 Patient monitor, Shenzhen Mindray Bio-medical Electronics (The primary predicate device)</td></tr>
<tr><td></td><td colspan="3">K112877, C80 COMEN Multi-parameter Patient Monitor, Shenzhen Comen Medical Instruments Co., Ltd</td></tr>
<tr><td>Device description:</td><td colspan="3">C30 Multi-parameter Patient Monitor (hereinafter called Patient Monitor) is intended to be used for monitoring, reviewing and storing of multiple physiological parameters as following: ECG, heart rate (HR), respiration (Resp), temperature (Temp), SpO_2, pulse rate (PR), non-invasive blood pressure (NIBP) of single patient. Other parameters can be applied to adult, pediatric or neonate.</td></tr>
<tr><td>Indications for Use:</td><td colspan="3">C30 Multi-parameter Patient Monitor (hereinafter called Patient Monitor) is indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. It’s used for monitoring, reviewing and storing of multiple physiological parameters as following: ECG, heart rate (HR), respiration (Resp), temperature (Temp), SpO2, pulse rate (PR), non-invasive blood pressure (NIBP) of single patient. All parameters can be applied to adult, pediatric or neonate. The Patient Monitor is not intended to be used on the patients with pacemaker. The monitor is used for monitoring the clinical patients, so only the doctors and nurses who are qualified through training can use these monitors.
The table below lists the patient population for each parameter as appropriate:
<table>
<tr><td>Patient Population / Parameter</td><td>Adult</td><td>Pediatric</td><td>Neonate</td></tr>
<tr><td>ECG</td><td>√</td><td>√</td><td>√</td></tr>
<tr><td>RESP</td><td>√</td><td>√</td><td>√</td></tr>
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</td></tr>
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<table>
<tr><td></td><td>
<table>
<tr><td>SpO2</td><td>√</td><td>√</td><td>√</td></tr>
<tr><td>TEMP</td><td>√</td><td>√</td><td>√</td></tr>
<tr><td>NIBP</td><td>√</td><td>√</td><td>√</td></tr>
<tr><td>Et CO2</td><td>√</td><td>√</td><td>√</td></tr>
<tr><td>Remark:</td><td colspan="3">1.The patient population for each parameter as appropriate is marked with '√';
2. The neonatal patient type is not included in the patient type of pediatrics for COMEN multi-parameter patient monitors.</td></tr>
</table>
</td></tr>
<tr><td>Indications for Use Comparison to Predicate Devices</td><td>The C30 and the predicate devices' indications for use are similar. The subject and predicate devices are all patient monitors that are intended to be used in healthcare facilities by physicians or clinical staff. The devices measure similar patient parameters.
The device provides single patient monitoring for parameters such as ECG, impedance respiration (Resp), temperature (TEMP),SpO2, pulse rate(PR), noninvasive blood pressure (NIBP), respiration rate (RR) and EtCO2. All parameters can be applied to adult, pediatric or neonate..

These minor differences between the predicate device and subject devices' indications for use do not constitute a new intended use and are not significant changes in indications for use.</td></tr>
<tr><td>Technological Comparison to Predicate Devices:</td><td>Both the subject devices and the predicate devices provide a means for interfacing with a patient, collecting parameter and specific physiological data, and processing the data for alarm generation and display of numeric values and waveforms.</td></tr>
</table>

Feature	Subject Devices	Predicate Device(primary) K123074	Predicate Device K112877
	C30	T1	C80
Dimension	190×82×105mm	143×77×102mm	344.5×291×165 mm
Integrated display and touchscreen	4.3'' 480*272 pixels	5'' same	12.1'' 800*600 pixels
Power supply	One standard rechargeable lithium-ion battery or AC power	Same	Same
Battery	11.1V, 2600mAh	14.8V, 4400Ah	12V, 2500mAh
ECG	3-lead, 5-lead or 12-lead selectable,	3-lead, 5-lead or 12-lead selectable, arrhythmia detection, ST segment	3-lead, 5-lead or 12-lead selectable
ECG measurement range and accuracy	HR: Neonate / Pediatric: 15 to 350bpm Adult: 15 to 300bpm Accuracy: ±1% or ±1bpm, whichever is the larger.	Same	Same
Respiration rate (Resp)	Measurement range: Adult: 7 to 120rpm, Neonate: 7 to 150rpm. Accuracy: 7 to 150 rpm: ±2rpm or ±2%, whichever is greater; 0 to 6rpm: Not specified.	Measurement range: Adult: 0 to 120rpm, Neonate: 0 to 150rpm. Accuracy: same	Measurement range: same Accuracy: 7 to 150rpm: ±1rpm
Temperature (Temp)	Measurement range: 0 to 50℃(32 to 122℉) Accuracy: ±0.1℃ or	Same	Same

			±0.2℉ (without probe)		
		Pulse oxygen saturation (SpO2)	Masimo SpO2 Module: Measurement range: 1 to 100% Accuracy: 70 to 100%: ±2% (measured without motion in adult/pediatric mode) Accuracy: 70 to 100%: ±3% (measured without motion in neonate mode) Accuracy: 70 to 100%: ±3% (measured with motion) 1 to 69%: Not specified NellcorSpO2 module: Measurement range: 0 to 100% Accuracy: 70 to 100%: ±2% (adult/pediatric mode) Accuracy: 70 to 100%: ±3% (neonate mode) 0 to 69%: Not specified	MindarySpO2 Module: Measurement range: 0 to 100% Accuracy: 70 to 100%: ±2% (adult/pediatric mode) 70 to 100%: ±3% (neonate mode) 0 to 69%: Not specified Masimo SpO2 Module: Same NellcorSpO2 module: Same	Masimo SpO2 Module: Same NellcorSpO2 module: Same
		Pulse rate	PR from MasimoSpO2 module: Measurement	PR from MindarySpO2 module: Measurement	/

			range: 25 to 240 bpm Accuracy: ±3bpm (measured without motion) ±5 bpm (measured with motion) PR from NellcorSpO2 module: Measurement range: 20 to 300 bpm Accuracy: 20 to 250bpm: ±3bpm, 251 to 300bpm:not specified.	range: 20 to 254 bpm Accuracy: ±3bpm PR from MasimoSpO2 module: Same PR from NellcorSpO2 module: Same	
		Non-invasive blood pressure (NIBP)	Measurement range: Adult: Systolic: 40-270mmHg Mean: / Diastolic: 10-215mmHg Pediatric: Systolic: 40-200mmHg Mean: / Diastolic: 10-150mmHg Neonate: Systolic: 40-135mmHg Mean: / Diastolic: 10-100mmHg Accuracy: Max mean error:	Measurement range: Adult: Systolic: same Mean: 20-230 Diastolic: 10-210mmHg Pediatric: Systolic: same Mean: 20-165mmHg Diastolic: same Neonate: Systolic: same Mean: 20-110mmHg Diastolic: 10-110mmHg Accuracy: Same	Measurement range: Adult: Systolic: same Mean: 20-235 Diastolic: same Pediatric: Systolic: same Mean: 20-165mmHg Diastolic: 10-100mmHg Neonate: Systolic: 40-150mmHg Mean: 20-110mmHg Diastolic: same Accuracy: Same

			±5mmHg Max standard deviation: 8mmHg		
		Carbon dioxide (CO2)	Respironics Novametrix CO2 module: Measurement range: 0-150mmHg, Accuracy: 0-40mmHg: ±2mmHg 41-70mmHg: ±5% of the reading 71-100mmHg: ±8% of the reading 101-150mmHg: ±10% of the reading awRR measurement range: 0 to 150 rpm awRR measurement accuracy: ±1rpm Masimo CO2 module: Measurement range: 0-190mmHg Accuracy: 0-114mmHg: ±1.52mmHg+2% 114mmHg-190mmHg: Not specified awRR measurement range: 0 to 150 rpm awRR measurement accuracy: ±1rpm	Measurement range: 0-99mmHg Accuracy: 0 to 40 mmHg: ±2mmHg 41 to 76mmHg: ±5% of the reading 77 to 99mmHg: ±10% of the reading awRR measurement range: 0 to 120 rpm awRR measurement accuracy: ±2rpm	/

	The differences do not raise questions of safety and effectiveness
Summary of Performance Testing:	The C30 Multi-parameter Patient Monitor has been tested and found to be in compliance with recognized safety, performance and electromagnetic compatibility standards. The risk analysis has been developed to identify potential hazards and documents the mitigation of the hazards. The device's software has been verified and validated in accordance with the appropriate test requirements. Clinical and/or bench performance testing are also provided. The C30 Multi-parameter Patient Monitor has been evaluated by end-users and found to meets performed within its intended use and met their specific needs. The C30 Multi-parameter Patient Monitor has been tested and found to be in compliance with the following safety, performance and electromagnetic compatibility standards: **Electrical Safety and Electromagnetic Compatibility:** ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 IEC 60601-1-2:2007 **Bench testing:** IEC 60601-1-8 Edition 2.0 2006-10 IEC60601-2-27 Edition 3.0 2011-03 IEC 80601-2-30 Edition 1.1 2013-07 IEC 80601-2-56 First Edition 2009-10-01 IEC 80601-2-61 First Edition 2011-04-01 IEC 62366-1 Edition 1.0 2015-01 ISO 80601-2-55 First Edition 2011-12-15 **Clinical testing:**

	According to ISO 81060-2:2013, NIBP clinical accuracy was verified. To verify respiration rate (RR) accuracy, Clinical study was conducted comparing the RR from the subject device with that from capnography. **Software Verification and Validation Testing:** The software was developed according to IEC 62304 First Edition 2006-05. Testing was conducted to verify and validate the software performs according to the requirements. Documentation in accordance with FDA's guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" was provided.
Conclusion:	Based on similarities in intended use and technological characteristics, results of performance and validation/verification testing, and conformance with applicable standards, the C30 Multi-parameter Patient Monitor is considered substantially equivalent to the predicate devices.