December 13, 2019

Shenzhen Comen Medical Instruments Co., Ltd.
Hongbo Yan
Regulation Engineer
Floor 11 and Section C of Floor 12 of Building 1A & Floor 1
To Floor 5 of Building 2, FIYTA Timepiece Bldg, Nanhuan Ave.
Shenzhen, 518106 China

Re: K191106
Trade/Device Name: C50 and C80 Multi-parameter Patient Monitor
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (Including ST-Segment Measurement And Alarm)
Regulatory Class: Class II
Product Code: MHX, DSI, MLD, DRT, DSJ, DXN, DSK, DPS, DXG, DSB, FLL, DQA, CCK, CBQ, CBS, CBR, CCL, NHO, NHP, OLW, GXY
Dated: November 15, 2019
Received: November 15, 2019

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Jessica Paulsen
Director
Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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)*
K191106

Device Name
C50 and C80 Multi-parameter Patient Monitor

Indications for Use *(Describe)*
The C50 and C80 patient monitors are intended to be used for monitoring, displaying, reviewing, alarming and storing of multiple physiological parameters as following: ECG (3-lead , 5-lead or 12-lead selectable, arrhythmia detection, heart rate (HR)), Respiration rate (RR), SpO2, pulse rate (PR), non-invasive blood pressure (NIBP), temperature (Temp), invasive blood pressure (IBP), carbon dioxide (CO2), anesthetic gas (AG), cardiac output (C.O.) for single patient. The C80 can also monitor the ICG (impedance cardiography) and BIS (bispectral index).
All the parameters can be monitored on single adult, pediatric, and neonatal patients with the exception of the following:
• The ICG monitoring is applicable to the adult patients of 122~229cm in height and 30~159Kg (67~341 pounds) in weight only;
• NIBP measurement continual mode is not applicable to neonates;
• Anesthetic depth (BIS) of the multi-parameter patient monitor is not intended for neonatal patients;
The monitors are to be used in general healthcare facilities by clinical physicians or appropriate medical staff under the direction of physicians. The monitors are not intended for home use.

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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Section 5 - 510 (k) Summary

C50 and C80 Multi-parameter Patient Monitor

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

Date:	September 26, 2019		
Submitter	SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD		
Address	Floor 11 and Section C of Floor 12 of Building 1A & Floor 1 to Floor 5 of Building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, 518106, Guangdong, China.		
Contact	Hongbo Yan		
Telephone	+86-13424152596		
Facsimile	+86-755-23431232		
Device trade name	C50 and C80 Multi-parameter Patient Monitor		
Common name	Multi-parameter Patient Monitor		
Classification Regulation, Classification name and Product Codes			
Device Panel	Regulation number &Classification	Procode	Description
Cardiovascular	§870.1025, II	MHX	Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Cardiovascular	§870.1025, II	DSI	Arrhythmia detector and alarm (including ST-segment measurement and alarm).
Cardiovascular	§870.1025, II	MLD	Arrhythmia detector and alarm (including ST-segment measurement and alarm).
Cardiovascular	§870.2300, II	DRT	Monitor, Cardiac (Incl. Cardiotachometer& Rate Alarm)
Cardiovascular	§870.1100, II	DSJ	Alarm, Blood-Pressure
Cardiovascular	§870.1130, II	DXN	System, Measurement, Blood-Pressure, Non-Invasive
Cardiovascular	§870.1110, II	DSK	Computer, Blood-Pressure
Cardiovascular	§870.2340, II	DPS	Electrocardiograph
Cardiovascular	§870.1435, II	DXG	Computer, Diagnostic, Pre-Programmed, Single-Function
Cardiovascular	§870.2770, II	DSB	Plethysmograph, Impedance
General Hospital	§880.2910, II	FLL	Thermometer, Electronic, Clinical
Anesthesiology	§870.2700, II	DQA	Oximeter
Anesthesiology	§868.1400, II	CCK	Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase
Anesthesiology	§868.1500, II	CBQ	Analyzer, Gas, Enflurane, Gaseous-Phase (Anesthetic Concentration)

Anesthesiology	§868.1620, II	CBS	Analyzer, Gas, Halothane, Gaseous-Phase (Anesthetic Conc.)
Anesthesiology	§868.1700, II	CBR	Analyzer, Gas, Nitrous-Oxide, Gaseous Phase (Anesthetic Conc.)
Anesthesiology	§868.1720, II	CCL	Analyzer, Gas, Oxygen, Gaseous-Phase
Anesthesiology	§868.1500, II	NHQ	Analyzer, Gas, Isoflurane, Gaseous-Phase (Anesthetic Concentration)
Anesthesiology	§868.1500, II	NHO	Analyzer, Gas, Desflurane, Gaseous-Phase (Anesthetic Concentration)
Anesthesiology	§868.1500, II	NHP	Analyzer, Gas, Sevoflurane, Gaseous-Phase (Anesthetic Concentration)
Neurology	§882.1320, II	GXY	Electrode, Cutaneous
Predicate Device:	K170876, Passport Series Patient Monitors (Passport 12m and Passport 17m), Shenzhen Mindray Bio-medical Electronics Co., LTD		
Device description:	The C50 and C80 patient monitors are intended to be used for monitoring, displaying, reviewing, alarming and storing of multiple physiological parameters as following: ECG (3-lead , 5-lead or 12-lead selectable, arrhythmia detection, heart rate (HR)), Respiration rate (RR), SpO2, pulse rate (PR), non-invasive blood pressure (NIBP), temperature (Temp), invasive blood pressure (IBP), carbon dioxide (CO2), anesthetic gas (AG), cardiac output (C.O.) for single patient. The C80 can also monitor the ICG (impedance cardiography) and BIS (bispectral index). All the parameters can be monitored on single adult, pediatric, and neonatal patients with the exception of the following: • The ICG monitoring is applicable to the adult patients of 122~229cm in height and 30~159Kg (67~341 pounds) in weight only; • NIBP measurement continual mode is not applicable to neonates; • Anesthetic depth (BIS) of the multi-parameter patient monitor is not intended for neonatal patients; Those monitors provide patient monitoring capabilities by using corresponding accessories. The multi-parameter Patient monitor, model: C50 and C80 have same design principle and technical characteristics: But the software in the host and modules and components are different. The differences between C50 and C80 are ICG, BIS and size of monitor.		
Indications for Use:	The C50 and C80 patient monitors are intended to be used for monitoring, displaying, reviewing, alarming and storing of multiple physiological parameters as following: ECG (3-lead , 5-lead or 12-lead selectable, arrhythmia detection, heart rate (HR)), Respiration rate (RR), SpO2, pulse rate (PR), non-invasive blood pressure (NIBP), temperature (Temp), invasive blood pressure (IBP), carbon dioxide (CO2), anesthetic gas (AG),		

<table>
<tr><td></td><td>cardiac output (C.O.) for single patient. The C80 can also monitor the ICG (impedance cardiography) and BIS (bispectral index).

All the parameters can be monitored on single adult, pediatric, and neonatal patients with the exception of the following:
• The ICG monitoring is applicable to the adult patients of 122~229cm in height and 30~159Kg (67~341 pounds) in weight only;
• NIBP measurement continual mode is not applicable to neonates;
• Anesthetic depth (BIS) of the multi-parameter patient monitor is not intended for neonatal patients;
The monitors are to be used in general healthcare facilities by clinical physicians or appropriate medical staff under the direction of physicians. The monitors are not intended for home 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.
The device respecting indications for use, basic operation and performance specifications of the C50 and C80 Multi-parameter Patient Monitor is equivalent to Passport Series Patient Monitors (K170876). Those devices all can provide monitoring such as ECG (3-lead , 5-lead or 12-lead selectable, arrhythmia detection, heart rate (HR)), Respiration rate (RR), SpO2, pulse rate (PR), non-invasive blood pressure (NIBP), temperature (Temp), invasive blood pressure (IBP), carbon dioxide (CO2), anesthetic gas (AG), cardiac output (C.O.) for single patient. The C80 can also monitor the ICG (impedance cardiography) and BIS (bispectral index).
All the parameters can be monitored on single adult, pediatric, and neonatal patients with the exception of the following:
• The ICG monitoring is applicable to the adult patients of 122~229cm in height and 30~159Kg (67~341 pounds) in weight only;
• NIBP measurement continual mode is not applicable to neonates;
• Anesthetic depth (BIS) of the multi-parameter patient monitor is not intended for neonatal patients;

Table below compares the key technological feature of the subject devices (C50 and C80 patient monitors) to the predicate device (K170876, Passport 12m and Passport 17m). The features in yellow are the features that are same with the predicate device.
Device Comparison Table
<table>
<tr><td></td><td>Predicate device(K170876)</td><td>Subject devices</td><td>Comparison</td></tr>
<tr><td>Feature</td><td>Passport 12m/17m</td><td>C50 and C80</td><td>/</td></tr>
<tr><td>Monitor Size</td><td>Passport 17m:400 mm×370 mm×193mm
Passport 12m:
297 mm × 336 mm × 187mm</td><td>C80: About 344mm×291 mm×165mm
C50: About 291.7mm × 250</td><td>The monitor size of subject device is smaller than predicate device, but it won’t affect</td></tr>
</table>
</td></tr>
</table>

				mm × 146.5mm	the safety and effectiveness of subject device.
	Integrated display and touch screen	color TFT LCD	color TFT LCD	same	
		Passport 17m: 17 Inch Passport 12m:12 Inch	C80: Size: 12.1 Inch C50: Size: 10.4 Inch	The screen of Subject device is smaller than predicate device, Complying with IEC 60601-1 and IEC 62366-1 also indicates the clinical use is safe and effective..	
		Passport 17m: 1280×1024 pixels Passport 12m: 800×600 pixels	C80 Pixel :800×600 C50 Pixel :800×600		
	Power supply	Passport 17m: Two rechargeable Lithium-ion battery or AC power supply Passport 112m: One rechargeable Lithium-ion battery or AC power supply	C50 and C80: Powered either by built-in battery or external AC.	Same, both powered by battery and AC.	
	Battery	11.1V, 4500mAh	11.1V, 2200mAh/4400mAh	The battery capacity is different. The batteries of C50/C80 have complied with IEC 62133. C50 and C80 have conformed to IEC 60601-1.	
	ECG	3-lead, 5-lead and 12-lead selectable, heart rate (HR)	3-lead, 5-lead and 12-lead selectable, heart rate (HR)	Same	
	ECG (Arrhythmia Analysis)	Asystole, VFib/VTac, Vtac, Vent. Brady, Extreme Tachy, Extreme Brady, PVC, Couplet, Bigeminy, Trigeminy, Ron T, Run PVCs, PVCs, Tachy, Brady,	Asystole, ventricular fibrillation, R ON T, VT>2, Couplet, PVC, Bigeminy, Trigeminy, Brady (Bradycardia), PNC (Pacer Not Capture), PNP	C50/C80 has 20 types of arrhythmias in total, 18 of which is same as the predicate device. The other two (underline) is supported by	

			Missed Beats, Vent. Rhythm, PNP, PNC, Multif. PVC, Nonsus. Vtac, Pause, Irr. Rhythm, AFib	(Pacer Not Pace), Missed Beats, IHB (Irregular Heart Beat), VTAC (Ventricular Tachycardia), Tachy (Tachycardia), PVCs Too High, Extreme Tachycardia, Extreme Bradycardia, Ventricular Rhythm, Heart Pause	compliance with EC57.	
		Respiration	Method: Trans-thoracic impedance Range: adult:0-120 rpm; pediatrics:0-150rpm; neonate:0-150rpm Accuracy: 7 to 150rpm: ±2rpm or ±2%, whichever is greater. 0 to 6rpm: not specified	Method: Trans-thoracic impedance Range: adult:0-120 rpm; pediatrics:0-150rpm ; neonate:0-150rpm Accuracy: 7 to 150rpm: ±2rpm or ±2%, whichever is greater. 0 to 6rpm: not specified	same	
		Pulse oxygen saturation (SpO2)	Method:red and infrared light method **Masimo SpO2:** Range:1~100% Accuracy: No motion Conditions: 70 to 100%: ±2%(in adult/pediatric mode) 70 to 100%: ±3% (in neonate mode) Motion conditions: 70%~100%: ±3% 1%~ 69%: Not specified. **Nellcor SpO2:** Range: 0~100% Accuracy:70% to	Method: same Masimo SpO2: Range: same Accuracy: same **Nellcor SpO2:** Range: same Accuracy: same **Comen SpO2:** Range: 0%-100% Accuracy: 70 to 100%: ±2% (adult/pediatric, in non-motion) 70 to 100%: ±3% (neonate, in non-motion) 0% to 69%: Not	same	

		100%: ±2% (adult/pediatric) 70 to 100%: ±3% (neonate) 0% to 69%: Not specified. **Mindray SpO2:** Measurement range: 0 to 100% Accuracy:70 to 100%: ±2% (adult/pediatric mode) 70 to 100%: ±3% (neonate mode) 0% to 69%: Not specified.	specified.		
	Pulse rate(PR)	**PR from Mindray SpO2 Module** Measurement range: 20 to 254 bpm Accuracy:±3 bpm **PR FROM Masimo SpO2:** Range: 25~240bpm Accuracy: ±3bpm (without motion) ±5bpm (with motion) **PR FROM Nellcor SpO2:** Range:20~300bpm Accuracy: 20~250bpm: ±3bpm 251~300bpm: not specified. **PR FROM IBP sensor:** Range:25-350bpm Accuracy:±1bpm or ±1%, whichever is greater	**PR FROM Masimo SpO2:** Range: 25~240bpm Accuracy: ±3bpm (without motion) ±5bpm (with motion) **PR FROM Nellcor SpO2:** Range: 20~300bpm Accuracy: 20~250bpm: ±3bpm 251~300bpm: not specified. **PR FROM Comen SpO2:** Range:20bpm~254bpm Accuracy: ±2bpm **PR FROM IBP sensor:** Range: 25-350bpm Accuracy: ±1bpm or ±1%, whichever is greater **PR FROM NIBP**	The PR from Comen SpO2 is more accuracy than the PR form Mindray SpO2. The PR form Masimo SpO2, Nellcor SpO2 and IBP sensor of C50 and C80 are the same with the predicate device. In addition, C50 and C80 have one more PR data source (NIBP) than predicate device. C50 and C80 have complied with ISO 80601-2-61.	

				sensor: Range:40bpm~240bpm; Accuracy: ±3bpm or ±3%, whichever is greater.	
	Non-invasive blood pressure (NIBP)	Method: Oscillometry Range: Adult: systolic:25 ~ 290mmHg diastolic:10~250mmHg pediatrics: systolic:25 ~ 240mmHg diastolic:10~200mmHg Neonate: systolic:25 ~ 140mmHg diastolic:10~115mmHg Accuracy: Max mean error: ±5 mmHg Max standard deviation: 8 mmHg	Method: same Range: Adult: systolic: 40-270mmHg diastolic: 10-215mmHg pediatrics: systolic:40~200mmHg diastolic:10~150mmHg Neonate: systolic:40~135mmHg diastolic:10~100mmHg Accuracy: 0~300mmHg: ±3mmHg	The NIBP measure range for adult/pediatric/neonate in C50 and C80 is smaller than that in predicate device. The C50 and C80 is more accuracy than predicate device. C50 and C80 have conformed to IEC 80601-2-30.
	Temperature(Temp)	Method:Thermal resistance Range: 0 ~ 50℃ Accuracy: ±0.1℃	Method: Thermal resistance Range: 0 ~ 50℃ Accuracy: ±0.2℃	The predicate device is more accuracy than C50 and C80. C50 and C80 have complied with ISO 80601-2-56.
	Carbon dioxide (CO2)	Method: Infrared absorption **Masimo CO2:** Range: **Sidestream CO2 Module:** 0~99mmHg AwRR:0~120rpm **Microstream CO2 Module**:	Method: same **Masimo CO2Range:** **Sidestream CO2 Module** 0mmHg~190mmHg, 0~25% (at 760mmHg) AwRR:0~150rpm **Mainstream CO2**	The C50 and C80 are more accuracy and measured wider than predicate device For C50 and C80, Masimo CO2 module (K123043 and K103604) and Respironics CO2

			0~99mmHg AwRR:0~150rpm **Accuracy:** **Sidestream CO2 Module:** 0 to 40 mmHg: ±2mmHg 41 to 76mmHg: ±5% of the reading 77 to 99mmHg: ±10% of the reading AwRR: ±2 rpm **Microstream CO2 Module** 0 to 38 mmHg: ±2mmHg 39 to 99mmHg: ±5% of the reading+0.08% of (the reading-38) **AwRR:** 0-70rpm: ±1 rpm 71-120rpm: ±2 rpm 121-150rpm: ±3 rpm	**Module** 0mmHg~190mmHg, 0~25% (at 760mmHg) AwRR:0~150rpm **Respironics CO2**: Range: **Sidestream CO2 Module** 0~150mmHg 0%~19.7%(0~20.0kPa) AwRR: 0，2rpm ~150rpm **Mainstream CO2 Module** 0~150mmHg0%~19.7% (0~20.0kPa) AwRR: 0，2rpm ~150rpm **Accuracy:** **Masimo Sidestream CO2 Module** All environment: ±(2.25mmHg +reading×4%) AwRR: ±1 rpm **Masimo Mainstream CO2 Module** All environment: ±(2.25mmHg +reading×4%) AwRR: ±1 rpm **Respironics Sidestream CO2 Module** 0~40mmHg: ±2mmHg 41~70mmHg: ±5%×reading	module (K040183 and K053174) have been cleared. Both modules have complied with ISO 80601-2-55.	

				71~100mmHg: ±8%×reading 101~150mmHg: ±10%×reading AwRR: ±1 rpm **Respironics Mainstream CO2 Module** 0~40mmHg: ±2mmHg 41~70mmHg: ±5%×reading 71~100mmHg: ±8%×reading 101~150mmHg: ±10%×reading AwRR: ±1 rpm	
		invasive blood pressure(IBP)	Method: Direct invasive measurement Range: -50 to 300 mmHg Accuracy: ±2% or ±1 mmHg, whichever is greater (without sensor)	Method: Direct invasive measurement Range: -50 to 300 mmHg Accuracy: ±2% or ±1 mmHg, whichever is greater (without sensor)	same
		cardiac output (C.O.)	Method: Thermodilution method Range: 0.1 to 20 L/min Accuracy: ±5% or ±0.1 L /min, whichever is greater	Method: Thermodilution method Range: 0.1 to 20 L/min Accuracy: ±5% or ±0.1 L /min, whichever is greater	same
		anesthetic gas (AG)	Method: Infrared absorption Range: CO2 0%~30% N2O 0%~100% Hal 0%~30% Enf 0%~30% Iso 0%~30% Sev 0%~30% Des 0%~30%	Method: same Range: $CO_2$0%~25% N_2Osame Hal0%~25% Enf0%~25% Iso0%~25% Sev0%~25% Des0%~25%	For CO2/Enf/ Hal/Iso/Sev/Des, The measurement range of C50 and C80 is smaller than the predicate device. For awRR, the measurement range of C50 and

			O2 0%~100% awRR 2~100rpm Accuracy: CO2 ±0.3%ABS N2O±(8%REL+2%ABS) Other anesthetic gases: 8%REL	O_2same awRR0~150rpm Accuracy: $CO_2$0%～15%: ±(0.2kPa+reading×2%) 15%～25%:Not defined. N_2O±(2 kPa+reading×2%) Hal, Enf, Iso: 0%～8%: ±(0.15%+reading×5%) Not defined. Sev0%～10%:±(0.15%+reading×5%) Not defined. Des0%~22%:±(0.15%+reading×5%) Not defined. O_2±(1%+reading×2%) MasimoAG awRR±1rpm	C80 is better than the predicate device. The C50 and C80 are more accuracy than predicate device. The measurement range of C50 and C80 is enough for most environments; it won't affect the safety and effectiveness. The C50 and C80 supports two AG modules: MASIMO ISA AX+ Sidestream module and Masimo IRMA AX+ Mainstream module, both of them have been cleared in K103604.	
		BIS	Range: BIS, BIS L, BIS R:0-100 SQI, SQI L, SQI R: 0 to 100% EMG, EMG L, EMG R: 0 to 100 Db SR, SR L, SR R: 0 to 100% SEF, SEF L, SEF R: 0.5 to 30.0 Hz TP, TP L, TP R: 40 to 100 Db BC, BC L, BC R: 0 to 30 sBIS L, sBIS R: 0 to 10.0	Range and Accuracy: BIS: same; accuracy: 1%. SQI: same; accuracy: 1%. EMG: same; accuracy: 1%. ESR: 0~100%; accuracy: 1%.	The underline parameters are what C50 and C80 doesn't have. The BIS module and sensor have been cleared by FDA and its 510k numbers are K040183 and K002734.	

		Semg L, Semg R: 0 to 10.0 ASYM: 0 to 100%		
	ICG	Method: Indirect impedance cardiograph measurement Range: SV: 5 to 250 ml HR: 44 to 2m C.O. 1.4 to 15 L/min Accuracy: SV: Not specified. HR: ±2 bpm C.O. Not specified	Method: same Range: HR: 40~250bpm SV: 0~250mL C.O.:0~30L/min TFC: 5~150 /KΩ SVR:0~3500 dyn・s・cm-5 Accuracy: SV: Not specified. HR: ±2 bpm C.O. Not specified.	The underline parameter is what C50 and C80 doesn't have. The ICG electrode cable and sensors are all cleared by FDA, 510(k) number of which is K110645.

Substantial Equivalence Conclusion:
The above detailed comparison of specifications for each of the modifications to the predicate devices (Passport 12m and Passport 17m), and they are different in monitor size, touch screen, battery, specification of Arrhythmia analysis, Pulse rate, NIBP, Temperature, CO2, anesthetic gas, BIS and ICG function. But the performance testing and conformance with applicable standards showed the differences above do not raise questions of safety and effectiveness. The detailed analysis for the differences please refers to the 3rd column in the above table. Therefore, we declared that the C50 and C80 Multi-parameter Patient Monitors can be found substantially equivalent to the predicate device.

Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

All patient contacting accessories have been previously cleared except for the ECG cable, SpO2 probes and temperature probes. These items are either surface contacting for prolonged durations, or mucosal membrane contacting for limited duration. The recommending testing from FDA's 2016 biocompatibility guidance document "*Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*" for these contact types include cytotoxicity, sensitization, and irritation testing. These three tests were performed for each of the patient-contacting components.

Software Verification and Validation Testing

Software verification and validation testing was conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*." 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. The software of this device was considered as a "major" level of concern.

Electrical safety and electromagnetic compatibility(EMC)

Electrical safety and EMC testing were conducted on the C50 and C80 multi-parameter patient monitor, the following standards are found to comply:

- ANSI AAMI ES60601-1:2005/(R)2012 And A1:2012Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD), FDA Recognition Number: 19-4
- IEC 60601-1-2 Edition 4: 2014-02Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests, FDA Recognition Number: 19-8

Bench Testing

The C50 and C80 Multi-parameter Patient Monitor have been conducted functional and system level tests. The testing results showed that the devices meet specifications requirements and the performance of the device is equivalent to the predicate.
In addition, COMEN have conducted testing to ensure the subject devices meet relevant recognized consensus standards.

- IEC 60601-1-8 Edition 2.1 2012-11Medical Electrical Equipment - Part 1-8: General Requirements For Basic Safety And Essential Performance - Collateral Standard: General Requirements, Tests And Guidance For Alarm Systems In Medical Electrical Equipment And Medical Electrical Systems, FDA Recognition Number: 5-76
- IEC 60601-2-27 Edition 3.0 2011-03Medical Electrical Equipment - Part 2-27: Particular Requirements For The Basic Safety And Essential Performance Of Electrocardiographic Monitoring Equipment [Including: Corrigendum 1 (2012)], FDA Recognition Number: 3-126
- IEC 80601-2-30 Edition 1.1 2013-07Medical Electrical Equipment - Part 2-30: Particular Requirements For The Basic Safety And Essential Performance Of Automated Non-Invasive Sphygmomanometers, FDA Recognition Number: 3-152
- IEC 60601-2-34 Edition 3.0 2011-05Medical Electrical Equipment - Part 2-34: Particular Requirements For The Basic Safety, Including Essential Performance, Of Invasive Blood Pressure Monitoring Equipment, FDA Recognition Number:3-115
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	Respiratory Gas Monitors, FDA Recognition Number: 1-96 ● ISO 80601-2-56 Second Edition 2017-03Medical Electrical Equipment - Part 2-56: Particular Requirements for Basic Safety and Essential Performance of Clinical Thermometers for Body Temperature Measurement, FDA Recognition Number: 6-403 ● ISO 80601-2-61 First Edition 2011-04-01Medical Electrical Equipment - Part 2-61: Particular Requirements For Basic Safety And Essential Performance Of Pulse Oximeter Equipment, FDA Recognition Number: 1-85 ● IEC 60601-1-6 Edition 3.1 2013-10Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability, FDA Recognition Number: 5-89 ● IEC 62366-1 Edition 1.0 2015-02Medical Devices - Part 1: Application Of Usability Engineering To Medical Devices [Including CORRIGENDUM 1 (2016)], FDA Recognition Number: 5-114 ● ANSI AAMI IEC 62304 First Edition 2006-05Medical Device Software - Software Life Cycle Processes, FDA Recognition Number: 13-32 ● ISO 14971 Second Edition 2007-03-01Medical Devices - Application Of Risk Management To Medical Devices, FDA Recognition Number: 5-40 ● ANSI AAMI EC57:2012Testing And Reporting Performance Results Of Cardiac Rhythm And ST-Segment Measurement Algorithms, FDA Recognition Number: 3-118 ● ISO 81060-2 Second Edition 2013-05-01 Non-Invasive Sphygmomanometers - Part 2: Clinical Validation Of Automated Measurement Type, FDA Recognition Number: 3-122 **Clinical studies** Non-invasive Blood Pressure (NIBP) clinical tests and oxygen saturation (SpO2) measurement clinical tests were conducted. **NIBP clinical study-for adults and children** Clinical evaluation of the non-invasive blood pressure was performed on adults and children. The clinical study complies with the *81060-2 Second Edition 2013-05-01 Non-Invasive Sphygmomanometers - Part 2: Clinical Validation Of Automated Measurement Type*. The studies were conducted in *The Second Affiliated Hospital of Guangzhou Medical University* and *The First Affiliated Hospital of Guangzhou Traditional Chinese Medical University* from 2012 to 2013. 25 patients were enrolled, including 19 adults and 6 children. There are 10 men and 15 women. 6 patients are between the ages of 3-12, 2 patients are between the ages of 12-40, 10 patients are between the ages of 40-60, and 7 patients are above 60 years old. The results are accurate and reliable, and the repeated measurement consistency is in good condition, within the measurement range. Moreover, No adverse events and side effects were found in clinical trials. Therefore, the non-invasive blood pressure module installed on the patient's multi-parameter monitor passes this clinical trial and meets the requirements of clinical use. It is safe, effective and easy to operate.

	NIBP clinical study-for neonate and infants Clinical evaluation of the non-invasive blood pressure was also performed on neonate and infants. The clinical study complies with the 81060-2 Second Edition 2013-05-01 Non-Invasive Sphygmomanometers - Part 2: Clinical Validation Of Automated Measurement Type. The studies were conducted in The First Affiliated Hospital of Guangxi Medical University and The First Affiliated Hospital of Xinxiang Medical University from 2012 to 2013. Twenty subjects were enrolled, including ten males and ten females. 10 groups of data were collected for each subject, total of 200 groups of data. There are 13 subjects are less 29 days, 4 subjects are 29 days to 1 years old, 3 subjects are 1 to 3 years old. The results are accurate and reliable, and the repeated measurement consistency is in good condition, within the measurement range. Moreover, No adverse events and side effects were found in clinical trials. Therefore, the non-invasive blood pressure module installed on the patient's multi-parameter monitor passes this clinical trial and meets the requirements of clinical use. As well as being safe, effective and easy to operate. **SpO2 clinical study** Clinical evaluation of the oxygen saturation was performed on adults and neonates. The clinical study complies with the *Pulse Oximeters-Premarket Notification Submissions[510(k)s], FDA Certification Guidance Document of Photoelectric Oximeter* and *ISO 80601-2-61 Medical Electrical Equipment - Part 2-61: Particular Requirements For Basic Safety And Essential Performance Of Pulse Oximeter Equipment*. The clinical study was conducted in the Affiliated Hospital of Guilin Medical University from January 20, 2016 to June 10, 2016. Twenty-four adult subjects are included in clinical trial aged from 24 years old to 44 years old (7 males and 17 females, 20 yellows and 4 blacks), With 6 neonates included aged from 1 day to 24 days (5 males and 1 female), there are 30 subjects in total were included in the tests. Per the clinical test analysis result, there is no adverse events, the oxygen saturation module and probe are safe and effective for the intended use, as well as demonstrating accurate pulse measurement. **Summary** Based on the non-clinical and clinical performance above, the C50 and C80 multi-parameter patient monitor was found to have a safety and effectiveness profile that is similar to the predicate device.
Conclusion:	The C50 and C80 Multi-parameter Patient Monitor are substantially equivalent to the predicate devices (Passport 12m and Passport 17m, K170876) indications for use, technical characteristics and performance. Performance testing results and conformance with applicable standards demonstrate that the C50 and C80 Multi-parameter Patient Monitor are as safe and effective for the intended use, and perform as well as the predicate device. According to the intended use, the software of C50 and C80 Multi-parameter Patient Monitor was designed and has been verified and validated in accordance with the appropriate test requirements. The accessories contacting with human body has been proved to be harmless by biocompatibility tests and/or 510(K) reports.

	Manufacturer suggests that the lifetime of the C50 and C80 Multi-parameter Patient Monitor is 5 years.