December 29, 2022

Shenzhen Comen Medical Instruments CO., LTD.
Charlotte Lin Jingfang
International Registration Engineer
FIYTA Timepiece Building, Nanhuan Avenue, Matian
Sub-District, Guangming District
Shenzhen, Guangdong 51806
China

Re: K211619
Trade/Device Name: 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, NHQ, NHO, NHP, OLW, GXY
Dated: December 2, 2022
Received: December 2, 2022

Dear Charlotte Lin Jingfang:

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 Shruti N. Mistry -S

Jennifer Shih Kozen
Assistant 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)*
K211619

Device Name
Multi-parameter Patient Monitor, model: NC10, NC12

Indications for Use *(Describe)*
The NC10 and NC12 patient monitors are intended to be used for monitoring, displaying, reviewing, alarming and storing of multiple physiological parameters. These parameters include ECG (3-lead, 5-lead or 12-lead selectable, arrhythmia detection, heart rate (HR)), Respiration rate (RR), temperature (Temp), SpO2, pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), cardiac output (C.O.), carbon dioxide (CO2), anesthetic gas (AG), and Bispectral index (BIS) for a single patient.
All parameters can be monitored on single adult, pediatric, and neonatal patients except:
• BIS monitoring is intended for adult and pediatric patients only;
• C.O. monitoring is restricted to adult patients only;
• Arrhythmia analysis is intended to use on adult patients only and is not intended and shall not be used on pediatric and neonatal population.
• When using COMEM SpO2, the monitor is intended to be used on adult patients only.
• NIBP measurement continual mode is not applicable to neonates.

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 helicopter transport, hospital ambulance, or home use.
The monitors do not measure, display, or trend changes in the ST segment.
The monitors do not intend for use as apnea monitors.
The monitors are not intended for use in MRI or CT environments.
The monitors are not used on patients who have a demonstrated need for cardiac monitoring known arrhythmias of VT, Accelerated Idioventricular rhythm and Torsades de Pointes.

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

NC10 and NC12 Multi-parameter Patient Monitor

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

Date:	2nd December, 2022
Submitter	SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD
Address	Floor 10, 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	Chuanqing Zhu
Telephone	+86-18252006698
Facsimile	+86-755-3431232
Ee-mail	zhuchuanqing@szcomen.com
Device trade name	NC10 and NC12 Multi-parameter Patient Monitor
Common name	Multi-parameter Patient Monitor

Classification Regulation, Classification name and Product Codes

Device Panel	Regulation number & Classification	Product code	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 (Including 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	§882.1400, II	OLW	Index-Generating Electroencephalograph Software
Neurology	§882.1320, II	GXY	Electrode, Cutaneous
Predicate Device:	K191106, C50 and C80 Multi-parameter Patient Monitors, SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD		
Device description:	The NC10 and NC12 patient monitors are intended to be used for monitoring, displaying, reviewing, alarming and storing multiple physiological parameters. These parameters include ECG (3-lead, 5-lead or 12-lead selectable, arrhythmia detection, heart rate (HR)), Respiration rate (RR), temperature (Temp), SpO2, pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), cardiac output (C.O.), carbon dioxide (CO_2), anesthetic gas (AG), and Bispectral index (BIS) for a single patient. All parameters can be monitored on single adult, pediatric, and neonatal patients except: • BIS monitoring is intended for adult patients only; • C.O. monitoring is restricted to adult patients only; • Arrhythmia analysis is intended for use with adult patients only and is not intended and shall not be used on pediatric and neonatal population. • When using COMEM SpO_2, the monitor is intended to be used on adult patients only. • NIBP measurement continual mode is not applicable to neonates. Both models are designed with: Same system framework and components Same hardware design principle Same software platform Same parameters measurement subsystems (including parameters modules and accessories) The only difference between NC10 and NC12 is the display size.		
Indications for Use:	The NC10 and NC12 patient monitors are intended to be used for monitoring, displaying, reviewing, alarming and storing of multiple physiological parameters. These parameters include ECG (3-lead, 5-lead or 12-lead selectable, arrhythmia detection, heart rate (HR)),		

	Respiration rate (RR), temperature (Temp), SpO_2, pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), cardiac output (C.O.), carbon dioxide (CO2), anesthetic gas (AG), and Bispectral index (BIS) for a single patient. All parameters can be monitored on single adult, pediatric, and neonatal patients except: • BIS monitoring is intended for adult and pediatric patients only; • C.O. monitoring is restricted to adult patients only; • Arrhythmia analysis is intended to use on adult patients only and is not intended and shall not be used on pediatric and neonatal population. • When using COMEM SpO_2, the monitor is intended to be used on adult patients only. • NIBP measurement continual mode is not applicable to neonates. 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 helicopter transport, hospital ambulance, or home use. The monitors do not measure, display, or trend changes in the ST segment. The monitors do not intend for use as apnea monitors. The monitors are not intended for use in MRI or CT environments. The monitors are not used on patients who have a demonstrated need for cardiac monitoring known arrhythmias of VT, Accelerated Idioventricular rhythm and Torsades de Pointes.
Technological Comparison to Predicate Devices:	Both the subject devices and the predicate device provide a means for monitoring one patient, collecting specific physiological data, processing the data for alarm conditions and display of numeric values and waveforms. In terms of indications for use, basic operation and performance specifications, the NC10 and NC12 Multi-parameter Patient Monitor is equivalent to C50 and C80 multi-parameter Patient Monitors (K191106). All devices can provide monitoring such as ECG(3-lead , 5-lead or 12-lead selectable, arrhythmia detection, heart rate (HR)), Respiration rate(RR), Temperature (Temp), SpO_2, pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), cardiac output (C.O.), carbon dioxide (CO2), anesthetic gas (AG) and Bispectral index (BIS)for a single patient. NC10 and NC12 restricted the arrhythmia analysis, BIS monitoring and COMEN SpO_2 on adults only, which is a subset of C50 and C80 multi-parameter patient monitor. These do not affect the substantial equivalence of subject device and predicate device. Table below compares the key technological feature of the subject devices (NC10 and NC12 patient monitors) to the predicate device (K191106, C50 and C80 multi-parameter patient monitor). The features in gray are features that are different between the predicate devices and the subject devices. **Device Comparison Table**

Feature	Predicate device C50 and C80 (K191106)	Subject devices NC10 and NC12	Comparison
Monitor Size	C80: 344mm×291 mm× 165mm C50: 291.7mm×250 mm×146.5mm	NC12: 308mm× 257 mm ×142mm NC10: 265mm ×227mm×141mm	Similar. Both devices met IEC 60601-1.
Integrated display screen	color TFT LCD	color TFT LCD	Same
	C80: 12.1 Inch C50: 10.4 Inch	NC12: 12.1 Inch NC10: 10.4 Inch	Same
	C80: 800×600 pixels C50: 800×600 pixels	NC12: Pixel: 800×600 NC10: Pixel: 800×600	Same
Power supply	C50 and C80: Two rechargeable Lithium-ion battery or AC power supply	NC10 and NC12: Two rechargeable Lithium-ion battery or AC power supply	Same
Battery	11.1V, 2200mAh or 4400mAh	11.1V, 2200mAh or 4400mAh	Same
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, ventricular fibrillation, R ON T, VT>2, Couplet, PVC, Bigeminy, Trigeminy, Brady (Bradycardia), PNC (Pacer Not Capture), PNP (Pacer Not Pace), Missed Beats, Heart Pause, Irregular Heart Beat, VTAC (Ventricular Tachycardia), Tachy (Tachycardia), PVCs Too High, Extreme Tachycardia, Extreme Bradycardia, Ventricular Rhythm,	Asystole, ventricular fibrillation, R ON T, VT>2, Couplet, PVC, Bigeminy, Trigeminy, Brady (Bradycardia), PNC (Pacer Not Capture), PNP (Pacer Not Pace), Missed Beats, Heart Pause, Irregular Heart Beat, VTAC (Ventricular Tachycardia), Tachy (Tachycardia), PVCs Too High, Extreme Tachycardia, Extreme Bradycardia, Ventricular Rhythm,	Same
Respiration	Method: Trans-thoracic impedance Range:	Method: Trans-thoracic impedance Range:	Same

		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	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	
	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.	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.	Same
		Nellcor SpO2: Range: 0~100% Accuracy:70 to 100%: ±2% (adult/pediatric) 70 to 100%: ±3% (neonate) 0% to 69%: Not specified.	**Nellcor SpO2:** Range: 0~100% Accuracy:70 to 100%: ±2% (adult/pediatric) 70 to 100%: ±3% (neonate) 0% to 69%: Not specified.	Same
		Comen SpO2: Range: 0 ~100%; Accuracy: 70 to 100%: ±2% (adult/pediatric mode) 70 to 100%: ±3% (neonate mode) 0% to 69%: Not specified	**Comen SpO2:** Range: 0 ~100%; Accuracy: 70 to 100%: ±3% (adult) 0% to 69%: Not specified	Different. The subject devices add exceptions on neonate and pediatric use of Comen SpO2. The SpO2 accuracy met ISO 80601-2-61 and was validated by the clinical study.

	Pulse rate(PR)	**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:** Range:25-350bpm Accuracy:±1bpm or ±1%, whichever is greater **PR FROM NIBP :** Range: 40 ~ 240 bpm; Accuracy: ±3bpm or ±3%, 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:** Range:25-350bpm Accuracy:±1bpm or ±1%, whichever is greater **PR FROM NIBP:** Range: 40 ~ 240 bpm; Accuracy: ±3bpm or ±3%, whichever is greater	Same	
	Non-invasive blood pressure (NIBP)	Method: Oscillometry Range: Adult: systolic:40-270 mmHg diastolic:10-215 mmHg pediatrics: systolic:40-200 mmHg diastolic:10-150 mmHg Neonate: systolic:40-140 mmHg diastolic:10-100 mmHg Error: Max mean error: ±5 mmHg	Method: Oscillometry Range: Adult: systolic: 40-270mmHg diastolic: 10-215mmHg pediatrics: systolic:40-200mmHg diastolic:10-150mmHg Neonate: systolic:40-135mmHg diastolic:10-100mmHg Error: Max mean error: ±5 mmHg	Same	

	Max standard deviation: 8 mmHg	Max standard deviation: 8 mmHg	
Temperature (Temp.)	Method: Thermal resistance Range: 0-50℃ Accuracy: ±0.1℃	Method: Thermal resistance Range: 0-50℃ Accuracy: ±0.1℃	Same
Carbon dioxide (CO2)	Method: Infrared absorption **Masimo Sidestream/ Mainstream CO2 Module:** **Range:** 0-190mmHg, 0~25% (at 760mmHg) AwRR:0~150rpm; Accuracy: All environment: 0mmHg~114mmHg: ±(2.25mmHg+reading×4%) 114 mmHg -190 mmHg: not defined. **Respironics Sidestream/Mainstream CO2 module:** Range: 0 mmHg ~150mmHg /0%~19.7% /0 kPa ~20.0kPa(at760mmHg) Accuracy: 0~40mmHg: ±2mmHg 41~70mmHg: ±5%×reading 71~100mmHg: ±8%×reading 101~150mmHg: ±10%×reading; awRR range: 0, 2~150bpm; Accuracy: ±1bpm	Method: Infrared absorption **Masimo Sidestream/ Mainstream CO2 Module:** **Range:** 0-190mmHg, 0~25% (at 760mmHg) AwRR:0~150rpm; Accuracy: All environment: 0mmHg~114mmHg: ±(2.25mmHg+reading×4%) 114 mmHg -190 mmHg: not defined. **Respironics Sidestream/Mainstream CO2 module:** Range: 0 mmHg ~150mmHg/ 0%~19.7% /0 kPa ~20.0kPa(at760mmHg) Accuracy: 0~40mmHg: ±2mmHg 41~70mmHg: ±5%×reading 71~100mmHg: ±8%×reading 101~150mmHg: ±10%×reading; awRR range: 0, 2~150bpm; Accuracy: ±1bpm	Same
invasive blood pressure(IBP)	Method: Direct invasive measurement Range: -50 to 300 mmHg	Method: Direct invasive measurement Range: -50 to 300 mmHg	Same

		Accuracy: ±2% or ±1 mmHg, whichever is greater (excluding the sensor error)	Accuracy: ±2% or ±1 mmHg, whichever is greater (excluding the sensor error)	
	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:** CO_2: 0%~25% N_2O: 0%~100% Hal: 0%~25% Enf: 0%~25% Iso: 0%~25% Sev: 0%~25% Des: 0%~25% O_2: 0%~100% awRR: 0~150rpm **Accuracy:** CO_2: 0%~15%: ±(0.2%+reading×2%) 15%~25%: Not defined. N_2O: ±(2%+reading×2%) Hal, Enf, Iso: 0%~8%:±(0.15 %+reading×5%) 8%-25%: Not defined. Sev: 0%-10%: ±(0.15 %+reading×5%) 10%~25%: Not defined. Des: 0%~22%: ±(0.15 %+reading×5%) 22%~25%: Not defined. O_2:±(1%+reading×2%) awRR: ±1rpm	Method: Infrared absorption **Range:** CO_2: 0%~25% N_2O: 0%~100% Hal: 0%~25% Enf: 0%~25% Iso: 0%~25% Sev: 0%~25% Des: 0%~25% O_2: 0%~100% awRR: 0~150rpm **Accuracy:** CO_2: 0%~15%: ±(0.2kPa+reading×2%) Not defined. N_2O: ±(2 kPa+ reading×2%) Hal, Enf, Iso: 0%~8%: ±(0.15%+reading×5%) Not defined. Sev: 0%-10%: ±(0.15%+reading×5%) Not defined. Des: 0%-22%: ±(0.15%+reading×5%) 22%~25%: Not defined. O_2: ±(1%+reading×2%) awRR: ±1rpm	Same

<table>
<tr><td></td><td>
<table>
<tr><td>BIS</td><td>Range and accuracy:
SQI: 0-100%; accuracy: 1%.
EMG: 0~100dB; accuracy: 1%.
BIS: 0-100; accuracy: 1%.
SR: 0~100%; accuracy: 1%.</td><td>Range and Accuracy:
BIS: 0-100; accuracy: 1%.
SQI: 0-100%; accuracy: 1%.
EMG: 0~100dB; accuracy: 1%.
ESR: 0~100%; accuracy: 1%.</td><td>Same</td></tr>
</table>

Substantial Equivalence Conclusion:
The above-detailed technical specification comparison for each parameter between the subject device and the predicate devices (C50 and C80 multi-parameter patient monitor) shows the difference lies in monitor size and Comen SpO_2. Therefore, we declared that the NC10 and NC12 Multi-parameter Patient Monitors can be found substantially equivalent to the predicate device.</td></tr>
<tr><td>Performance Data</td><td>The following performance data are provided to support the substantial equivalence determination.
Software Verification and Validation Testing
Software verification and validation testing were 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.”
Biocompatibility Testing
The accessories with patient contact have been evaluated by biocompatibility testing in accordance with ISO 10993-1.
Bench test
The NC10 and NC12 Multi-parameter Patient Monitor have been tested and found to be in compliance with the following safety, performance and electromagnetic compatibility standards:
● 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)
● IEC 60601-1-2 Edition 4.0: 2014-02 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests
● 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
● IEC 60601-2-27 Edition 3.0 2011-03 Medical Electrical Equipment - Part 2-27: Particular Requirements For The Basic Safety And Essential Performance Of Electrocardiographic Monitoring Equipment [Including: Corrigendum 1 (2012)]</td></tr>
</table>

	● IEC 80601-2-30: Edition 2.0 2018-03 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers ● IEC 60601-2-34 Edition 3.0 2011-05 Medical Electrical Equipment - Part 2-34: Particular Requirements For The Basic Safety, Including Essential Performance, Of Invasive Blood Pressure Monitoring Equipment ● ISO 80601-2-56 Second edition 2017-03 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. [Including: Amendment 1 (2018)]. ● ISO 80601-2-61 Second Edition 2017-12 Medical Electrical Equipment - Part 2-61: Particular Requirements For Basic Safety And Essential Performance Of Pulse Oximeter Equipment ● ISO 80601-2-55 Second Edition 2018-02 Medical Electrical Equipment - Part 2-55: Particular Requirements For The Basic Safety And Essential Performance Of Respiratory Gas Monitors ● ANSI AAMI EC57:2012 Testing And Reporting Performance Results Of Cardiac Rhythm And ST-Segment Measurement Algorithms ● IEC 80601-2-49:2018 Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment. ● IEC 80601-2-26:2019 Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs. ● EN 1060-1:1995+A2:2009 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type ● EN 1060-3:1997+A2:2009 Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems ● IEC 60601-1-6 Edition 3.1 2013-10 Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability ● IEC 62366-1 Edition 1.0 2015-02 Medical Devices - Part 1: Application Of Usability Engineering To Medical Devices [Including CORRIGENDUM 1 (2016)] ● ISO 14971 Third Edition 2019-12 Medical devices - Application of risk management to medical devices **Clinical studies** The clinical accuracy of non-invasive blood pressure (NIBP) determination, SpO_2 measurement, and respiratory rate were validated for the intended patient population. Clinical data is provided to support the determination of substantial equivalence with predicated devices that are currently marketed for the same intended use. • The accuracy of the SpO_2 accuracy during non-motion conditions as compared to CO-oximetry in a controlled desaturation study was validated using the method outlined in

	ISO 80601-2-61:2017 and the FDA guidance Pulse Oximeters - Premarket Notification Submissions [510(k)s]: Guidance for Industry and Food and Drug Administration Staff, March 2013. • The clinical accuracy of non-invasive blood pressure determination was validated according to ISO 81060-2 which contains the requirements for clinical accuracy and the protocols for investigating the NIBP determination clinical accuracy. • The clinical accuracy of respiratory rate was validated by clinical testing to compare the measurement of the subject device and that of a clinician-scored capnography device, manually scored end-tidal CO_2 ($EtCO_2$) capnography. All clinical accuracy validation studies were conducted in accordance with standard ISO 14155:2020. **Summary** Based on the non-clinical and clinical performance above, we demonstrate that the NC10 and NC12 multi-parameter patient monitors were substantially equivalent and perform as well as the predicate device.
Conclusion:	The NC10 and NC12 Multi-Parameter Patient Monitor are substantially equivalent to the predicate devices (C50 and C80 multi-parameter patient monitor, K191106) in terms of indication for use and technological characteristics. Performance testing and compliance with FDA-recognized consensus standards demonstrate that NC10/NC12 are substantially equivalent to the predicate device.