May 15, 2020

Medtronic Care Management Services
% Charmaine Sutton
Consultant
The Tamarack Group - MPLS, LLC
2584 Upton Ave. So
Minneapolis, Minnesota 55405

Re: K191745
Trade/Device Name: Commander Flex
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN, DQA, DRG
Dated: April 10, 2020
Received: April 14, 2020

Dear Charmaine Sutton:

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,

LT Stephen Browning
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)*
K191745

Device Name

Commander Flex

Indications for Use *(Describe)*

The Commander Flex is for use by patients to collect and transmit general health questions and patient vital sign data (such as weight, blood pressure, glucose, pulse oximetry) between the patient, typically at home, and a health care professional at a remote site.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510k Summary:

Medtronic Commander Flex Series remote patient monitoring device

Date Prepared: May 11, 2020

Submitter

Applicant: Medtronic Care Management Services
7980 Century Boulevard
Chanhassen, MN 55317
888-243-8881

Contact: Charmaine Dwyer (Sutton)
The Tamarack Group – MPLS, LLC
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Device Information

Trade Name: Medtronic Commander Flex
Model Numbers: CD300, CD300C, CD310, CD315, CD320
Common Name: Remote Patient Monitoring Device
Classification: Class II
Noninvasive Blood Pressure Measurement System – 21 CFR 870.1130
Oximeter – 21 CFR §870.2700
Product Codes DXN, DQA, DRG

Predicate Device(s)

	Primary Predicate	Secondary Predicate
Identification	Commander III Model CD3xx (Rx)	Tablet Commander Model TC200/TC210 (Rx and OTC)
Manufacturer	Cardiocom, LLC (now Medtronic)	Cardiocom LLC (now Medtronic)
510k number	K053303, K091821	K122285
Regulation number	21 CFR 870.1130 21 CFR 870.2700	21 CFR 870.2910
ProCode	DXN, DQA	DRG

Device Description

Commander Flex devices are home health monitoring tools typically used by patients with diseases such as congestive heart failure (CHF), diabetes, chronic obstructive pulmonary disease (COPD) asthma and coronary artery disease (CAD). Patients use Commander Flex to collect and send important health information to their health care team to allow a doctor and other health care team members to act before symptoms worsen.

Commander Flex devices have a built-in non-invasive blood pressure measurement system that measures systolic and diastolic blood pressure and pulse rate and displays the readings on the Commander Flex panel.

In addition to making blood pressure and heart rate measurements, Commander Flex devices store and transmit data from peripheral devices to remote locations. Commander Flex connects to a user's home phone line or cellular network. It has inputs for peripheral devices such as weight scales, glucose meters, pulse oximeters, thermometers and blood pressure cuff. The display asks health-related questions to obtain objective biometric data such as: weight, blood pressure, glucose, and pulse oximetry. Patients may also answer a series of questions about their current symptoms. The patient can respond Yes or No or select from a list. Commander Flex devices collect data from peripherals and transmit the data using a cellular connection or toll-free telephone number and modem. The modular design of the Commander Flex device allows for selection of the appropriate health monitoring devices for cost-effective patient care.

Commander Flex products are for home use. This 510(k) clearance achieves OTC designation for Commander Flex devices.

The peripheral devices are used as supplied by the manufacturer. The Commander Flex devices make no interpretation, evaluation, medical judgements or recommendations for treatment. Commander Flex is not used as an emergency response device. Clinical judgment and experience are required to interpret the information transmitted. Commander Flex devices are not intended as a substitute for medical care.

Intended Use

The Commander Flex is for use by patients to collect and transmit general health questions and patient vital sign data (such as weight, blood pressure, glucose, pulse oximetry) between the patient, typically at home, and a health care professional at a remote site.

Comparison to Predicate Devices

Regulatory and Intended Use Comparison

Feature	**Subject Device** Commander Flex Model CD300 -CD399 with OTC designation	**Primary Predicate** Commander III, Model CD300-CD399 K091821 & K053303	**Secondary Predicate** Tablet Commander Model TC200 -TC299 K122285	**Comparison**
510(k) Number		K091821 & K053303	K122285	--
Product Code & Classification Name	DXN System, Measurement, Blood Pressure, Non-Invasive DQA Oximeter	DXN System, Measurement, Blood Pressure, Non-Invasive DQA Oximeter	DRG Transmitters and Receivers, Physiological Signal, Radiofrequency	Same as primary
Class	Class II	Class II	Class II	Same
Regulation	21 CFR 870.1130 Non-Invasive Blood Pressure Measurement System	21 CFR 870.1130 Non-Invasive Blood Pressure Measurement System	21 CFR 870.2910 Radiofrequency Physiological Signal Transmitter and Receiver	Same as primary

Feature	Subject Device Commander Flex Model CD300 -CD399 with OTC designation	Primary Predicate Commander III, Model CD300-CD399 K091821 & K053303	Secondary Predicate Tablet Commander Model TC200 -TC299 K122285	Comparison
	21 CFR 870.2700 Oximeter	21 CFR 870.2700 Oximeter		
Intended Users	All three devices are used by home users and health care professionals			Same
Location of Use	All three devices are used in the home			Same
Rx/OTC	Rx & OTC	Rx	Rx & OTC	Same as secondary; same Rx as Primary
Intended Use	The Commander Flex is for use by patients to collect and transmit general health questions and patient vital sign data (such as weight, blood pressure, glucose, pulse oximetry) between the patient, typically at home, and a health care professional at a remote site.	The Commander III is for use by patients to collect and transmit general health questions and patient vital sign data (such as weight, blood pressure, glucose, pulse oximetry, peak flow) between the patient, typically at home, and a health care professional at a remote site.	The Tablet Commander device is for use by patients to collect and transmit general health information, physiological measurements and other data between themselves and a caregiver.	Same; all are for use by patients to collect and transmit general health information between themselves and a healthcare professional at a remote monitoring station
	All three devices make no interpretation, evaluation, medical judgments, or recommendations for treatment. Clinical judgment and experience are required to check and interpret the information transmitted, and they are not intended as a substitute for medical care.			Same

Technological and performance characteristics comparison

Feature	Subject Device Commander Flex Model CD300 -CD399 Series with OTC designation	Primary Predicate Commander III, Model CD300-CD399 Series K091821 & K053033	Secondary Predicate Tablet Commander Model TC200 -TC299 series K122285	Comparison
Basic Technology Description	The Commander Flex is an electronic device with built-in proprietary software. The Commander Flex also includes an integrated blood pressure measurement capability.	The Commander III is an electronic device with built-in proprietary software. The Commander III also includes an integrated blood pressure measurement capability.	The Tablet Commander is a software application capable of running on any hardware platform that uses the Android operating system.	Same as primary; similar to secondary
	All three devices interface with other electronic devices, including 510(k)-cleared or Class I exempt medical devices, using standard wired and wireless protocols to collect biometric data and communicate that data to a back-end database application using public communications (phone, cellular or Wi-Fi). All three use the same proprietary software to query and collect patient data.			Same

Feature	**Subject Device** Commander Flex Model CD300 -CD399 Series with OTC designation	**Primary Predicate** Commander III, Model CD300-CD399 Series K091821 & K053033	**Secondary Predicate** Tablet Commander Model TC200 -TC299 series K122285	**Comparison**
Device Software	Embedded firmware and patient database	Embedded firmware and patient database	Embedded software and patient database	Same as primary
	The software hazards for all three are: no data from peripheral, no data transmission to remote monitoring site, and corrupt data at remote monitoring site. The related risk is low because the patient data is used for trending and not to make immediate treatment decisions.			Same
Transmission / communication method	Cellular (network connectivity: CDMA or GPRS) or telephone modem (POTS)	Telephone modem (POTS)	Cellular (network connectivity: CDMA or GPRS)	Same as predicates, collectively
Security & Privacy	FIPS 140-2 Level 2 and native 4G/LTE encryption for cellular transmissions FIPS 140-2 Level 2 encryption for POTS (CD320 model)	Plain old telephone system (POTS)	FIPS Level 140-2 Level 2 encryption for WIFI transmissions	Subject device adds FIPS 140-2 encryption for cellular and POTS transmissions
Peripheral device interfaces	RS232 serial ports USB: 2.0 Radio frequency Supports battery charging of MCMS-approved peripherals via USB connection	RS232 serial ports	WIFI: 802.11 b/n/g USB: 2.0 Bluetooth: 3.0 Radio frequency Supports battery charging of MCMS-approved peripherals via USB connection	Same as predicates, collectively
	All three devices interface with the peripheral medical devices using standard connections according to protocols established by the manufacturer of the peripheral device. The protocols include checksums with re-transmit and purge loops for data validation. The list of compatible peripherals will change according to market demand, with each new peripheral being validated prior to making claims of compatibility.			Same
Built-in measurements	Non-invasive blood pressure reading using small, medium and large size cuffs	Non-invasive blood pressure reading using small, medium and large size cuffs	None	Same as primary
Power supply	All three use an external power supply that converts standard wall 120 volts AC to DC			Same
Electrical Safety	All three devices are tested to IEC 60601-1,2. The subject device is tested to the current version (2014).			Same
Communications compliance	All three devices comply with FCC Part 68.			Same
User Interface / Controls	All three communicate with patients using an on-screen LCD display in English, Spanish or both, enlarged font size, voice prompts, user input buttons or keys, quick			Same

Feature	Subject Device Commander Flex Model CD300 -CD399 Series with OTC designation	Primary Predicate Commander III, Model CD300-CD399 Series K091821 & K053033	Secondary Predicate Tablet Commander Model TC200 -TC299 series K122285	Comparison
	Start guide, user manuals, voice prompts, and customer support phone line 800 number.			
	physical keypad	physical keypad	virtual keypad / touchscreen	Same as primary
Cleanability	All three are designed to be cleaned using common household cleaning agents.			Same
Memory	Biometric data collection: all three devices can display past readings. Biometric review includes weight, blood pressure, glucose, oxygen saturation (and peak flow for the predicate device) Health check/subjective data: for all three devices only a single health check is stored in memory at a given time. If a new health check is taken the new answers will overwrite the previous answers. Answers are also removed from memory if the device successfully transmits a health check to the remote monitoring system. All three devices can read an external memory card.			Nearly identical; the subject device no longer supports a peak flow meter

Performance Data

Commander Flex devices are already used and labeled for use in the home, therefore no different or increased risks were identified by the OTC designation. Accordingly, no design changes, including no hardware, software or labeling changes were needed to support the OTC designation.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and electromagnetic compatibility (EMC) Electrical safety and EMC testing conducted on the Commander device showed the device complies with IEC 60601-1-2:2014 Ed.4 Electromagnetic Emissions and Immunity (EMC/EMI) and 80601-2-30 Medical Electrical Equipment - Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers.

Software verification and validation testing

The software for this device is considered a 'moderate' level of concern, since a failure or latent flaw in the software that controls the blood pressure circuit could directly result in minor injury to the patient or indirectly result in minor injury to the patient through incorrect or delayed information or through the action of a care provider. 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," including software risk assessments, software verification and validation testing. A cybersecurity threat assessment report was also provided.

Biomaterial safety information

The patient contact materials in the blood pressure cuff are identical to those in the predicate device, therefore no new biomaterial testing was needed to support substantial equivalence.

Human factors engineering information

Reports of usability engineering evaluations of Commander Flex devices, including use error analysis, user interface design analysis, and summative validation were provided. Usability test results show the user interface and user manual are sufficient for lay users to operate the device in a safe and effective manner.

A Use-Related Risk Assessment (URRA) was performed for Commander Flex devices to identify known or foreseeable user actions and identify risk-related use scenarios related to OTC use. The URRA included user profiles, task analysis, use error analysis, user interface design, and summative justification in accordance with FDA 2016 Guidance *Applying Human Factors and Usability Engineering to Medical Devices*. Commander Flex devices have been home-use devices for over a decade (under an Rx designation). The risk assessment revealed no different or increased risks and no new or additional critical tasks associated with the OTC designation. Therefore, additional Human Factors Validation Testing was deemed not necessary to support the Commander Series OTC designation.

Clinical data

Clinical testing of the Commander Flex blood pressure 2.0 algorithm in 99 human subjects (41% male; small, medium and large cuffs) was performed to measure the accuracy of the blood pressure measurement. Simultaneous blood pressure measurements were made by the Commander device and a trained observer using the stethoscope auscultatory method. The results demonstrate that the Commander blood pressure algorithm performance meets ANSI/AAMI SP10 and ISO 81060-2 requirements for sphygmomanometers.

Summary

Commander devices have always been used in the home. The updated performance evaluations revealed no new information about the safety and effectiveness profile of Commander. Device labeling was updated to reflect current standards. Commander devices with the OTC designation have a safety and effectiveness profile identical to the predicate device.

Conclusion

Commander Flex with the OTC designation has the same regulatory classifications, substantively the same intended use, the same environment of use, the same patient population and the same fundamental technology as the previously cleared Commander III devices. Commander Flex devices have no performance differences when compared to the predicate devices collectively and have been shown to meet all applicable industry standards. There are no new questions of safety or performance compared to the predicate devices. The information supplied demonstrates Commander Flex devices with the OTC designation have substantively the same intended use and the same technological characteristics as the previously cleared Commander III and Tablet Commander devices. Commander Flex devices with the OTC designation are, therefore, substantially equivalent to the legally marketed predicate devices.