December 13, 2023

GE Medical Systems Information Technologies, Inc.
Manjunatha Kn
Senior Regulatory Affairs Leader
9900 Innovation Drive
Wauwatosa, Wisconsin 53226

Re: K231870
Trade/Device Name: CASE V7.0 Cardiac Testing System and CardioSoft V7.0 Cardiac Testing System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: November 15, 2023
Received: November 15, 2023

Dear Manjunatha Kn:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jennifer W. Shih -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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231870

Device Name
CASE V7.0 Cardiac Testing System
CardioSoft V7.0 Cardiac Testing System

Indications for Use *(Describe)*
CASE V7.0 Cardiac Testing System and CardioSoft V7.0 Cardiac Testing System are intended to be used by trained operators under direct supervision of a licensed health care practitioner on adult and pediatric patients.

The CASE V7.0 Cardiac Testing System and CardioSoft V7.0 Cardiac Testing System are designed to acquire, process, record, archive, analyze and output (12 and 15 lead) ECG data during a period of physiologic stress or during a resting ECG test, acquire data from ancillary devices (such as Spirometry and Ambulatory Blood Pressure), provide median morphology recordings and record ECG in real-time with and without arrhythmia detection.

The arrhythmia detection portion of CASE V7.0 Cardiac Testing System and CardioSoft V7.0 Cardiac Testing System are provided to the user for the convenience of automatic detection of arrhythmias but do not provide alarms.

CASE V7.0 Cardiac Testing System and CardioSoft V7.0 Cardiac Testing System provide the control of external devices (typically a treadmill or bicycle ergometer) and communicate with centralized electronic/digital storage system via data networks.

CASE V7.0 Cardiac Testing System and CardioSoft V7.0 Cardiac Testing System provide a user selectable option for printouts of prognostic scores on selected reports. Vector loops are also available.

CASE V7.0 Cardiac Testing System and CardioSoft V7.0 Cardiac Testing System can be configured in a network environment for multiple CASE and CardioSoft stations allowing the user to create a central database of patient demographics and collected patient physiological data.

CASE V7.0 Cardiac Testing System and CardioSoft V7.0 Cardiac Testing System are intended to be used primarily in the hospital but can also be used in clinics, physician offices, outreach centers or wherever exercise, stress testing, ECG, Spirometry or ambulatory blood pressure testing is performed.

CASE V7.0 Cardiac Testing System and CardioSoft V7.0 Cardiac Testing System offer no diagnostic opinion to the user. Instead, it provides interpretive statements of morphology, rhythm, and conduction for which the physician renders his/her own medical opinion.

CASE V7.0 Cardiac Testing System and CardioSoft V7.0 Cardiac Testing System are not intended to be used as a transport device or for home use.

CASE V7.0 Cardiac Testing System and CardioSoft V7.0 Cardiac Testing System are not intended for use as a vital signs physiological monitor.

CASE V7.0 Cardiac Testing System and CardioSoft V7.0 Cardiac Testing System are not intended for intracardiac use.

CASE V7.0 Cardiac Testing System and CardioSoft V7.0 Cardiac Testing System are not intended for use as an emergency device.

CASE V7.0 Cardiac Testing System and CardioSoft V7.0 Cardiac Testing System will not cause abnormal operation of a patient's cardiac pacemaker or other electronic stimulators.

CASE V7.0 Cardiac Testing System and CardioSoft V7.0 Cardiac Testing System are not intended for use with high frequency surgical units. Disconnect the patient from CASE V7.0 Cardiac Testing System and CardioSoft V7.0 Cardiac Testing System before using the high frequency surgical unit.

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

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	01-June-2023
Submitter:	GE Medical Systems *Information Technologies*, Inc. 9900 Innovation Drive Wauwatosa, WI 53226
Primary Contact Person:	Manjunatha K N Senior Regulatory Affairs Leader GE Medical Systems *Information Technologies*, Inc. Phone: +91 (98453) 58045
Secondary Contact Person:	Shlomi Deler Regulatory Affairs Director GE Medical Systems *Information Technologies*, Inc. Phone: +(972) 544301056
Device Trade Name:	CASE V7.0 Cardiac Testing System CardioSoft V7.0 Cardiac Testing System
Common/Usual Name:	CASE V 7.0 / Cardiosoft V7.0
Classification Names:	Computer, diagnostic, programmable
Product Code:	DQK 21CFR.870.1425
Predicate Device(s):	CASE Cardiac Testing System, CS Cardiac Testing System (K103678)
Device Description:	The CASE V7.0 Cardiac Testing System and the CardioSoft V7.0 Cardiac Testing System are designed to be used for resting ECG, stress test ECG, Spirometry, Ambulatory Blood Pressure and for recording ECG in real-time with and without arrhythmia detection. The CardioSoft V7.0 Cardiac Testing System will be offered as a software only package including a front end for data acquisition. The

CASE V7.0 Cardiac Testing System is a turnkey product utilizing the CardioSoft V7.0 Cardiac Testing software.

Indications for Use:

CASE V7.0 Cardiac Testing System and CardioSoft V7.0 Cardiac Testing System are intended to be used by trained operators under direct supervision of a licensed health care practitioner on adult and pediatric patients.

The CASE V7.0 Cardiac Testing System and CardioSoft V7.0 Cardiac Testing System are designed to acquire, process, record, archive, analyze and output (12 and 15 lead) ECG data during a period of physiologic stress or during a resting ECG test, acquire data from ancillary devices (such as Spirometry and Ambulatory Blood Pressure), provide median morphology recordings and record ECG in real-time with and without arrhythmia detection.

The arrhythmia detection portion of CASE V7.0 Cardiac Testing System and CardioSoft V7.0 Cardiac Testing System are provided to the user for the convenience of automatic detection of arrhythmias but do not provide alarms.

CASE V7.0 Cardiac Testing System and CardioSoft V7.0 Cardiac Testing System provide the control of external devices (typically a treadmill or bicycle ergometer) and communicate with centralized electronic/digital storage system via data networks.

CASE V7.0 Cardiac Testing System and CardioSoft V7.0 Cardiac Testing System provide a user selectable option for printouts of prognostic scores on selected reports. Vector loops are also available.

CASE V7.0 Cardiac Testing System and CardioSoft V7.0 Cardiac Testing System can be configured in a network environment for multiple CASE and CardioSoft stations allowing the user to create a central database of patient demographics and collected patient physiological data.

CASE V7.0 Cardiac Testing System and CardioSoft V7.0 Cardiac Testing System are intended to be used primarily in the hospital but can also be used in clinics, physician offices, outreach centers or wherever exercise, stress testing, ECG, Spirometry or ambulatory blood pressure testing is performed.

CASE V7.0 Cardiac Testing System and CardioSoft V7.0 Cardiac Testing System offer no diagnostic opinion to the user. Instead, it provides interpretive statements of morphology, rhythm, and conduction for which the physician renders his/her own medical opinion.

	CASE V7.0 Cardiac Testing System and CardioSoft V7.0 Cardiac Testing System are not intended to be used as a transport device or for home use. CASE V7.0 Cardiac Testing System and CardioSoft V7.0 Cardiac Testing System are not intended for use as a vital signs physiological monitor. CASE V7.0 Cardiac Testing System and CardioSoft V7.0 Cardiac Testing System are not intended for intracardiac use. CASE V7.0 Cardiac Testing System and CardioSoft V7.0 Cardiac Testing System are not intended for use as an emergency device. CASE V7.0 Cardiac Testing System and CardioSoft V7.0 Cardiac Testing System will not cause abnormal operation of a patient's cardiac pacemaker or other electronic stimulators. CASE V7.0 Cardiac Testing System and CardioSoft V7.0 Cardiac Testing System are not intended for use with high frequency surgical units. Disconnect the patient from CASE V7.0 Cardiac Testing System and CardioSoft V7.0 Cardiac Testing System before using the high frequency surgical unit.
Technology:	CASE V7.0 Cardiac Testing System and the CardioSoft V7.0 Cardiac Testing System employ the same fundamental scientific technology, basic design, construction, materials, energy source, control mechanism, and operating principles as the predicate device CASE / CS Cardiac Testing System (K103678) to acquire, process, record, archive, analyze, and output (12 and 15 lead) ECG data during a period of physiologic stress or during a resting ECG test, acquire data from ancillary devices (such as Spirometry and Ambulatory Blood Pressure), provide median morphology recordings, and record ECG in real-time with and without arrhythmia detection.
Determination of Substantial Equivalence:	CASE V7.0 Cardiac Testing System and the CardioSoft V7.0 Cardiac Testing System is substantially equivalent to predicate device CASE / CS Cardiac Testing System (K103678) as described in the table below

Feature/Function	Predicate Device CASE V6.6 and CS V6.6 (K103678)	Proposed Device CASE V7.0 and CardioSoft V7.0	Explanation of Differences
Classification / Product Code	21CFR.870.1425 / DQK	21CFR.870.1425 / DQK	Identical
Intended Use Statement	CASE Cardiac Testing System and CS Cardiac Testing System are intended to be used by trained operators under direct supervision of a licensed health care practitioner on adult and pediatric patients. The CASE Cardiac Testing System and CS Cardiac Testing System are designed to acquire, process, record, archive, analyze and output (12 and 15 lead) ECG data during a period of physiologic stress or during a resting ECG test, acquire data from ancillary devices (such as Spirometry and Ambulatory Blood Pressure), provide median morphology recordings and record ECG in real-time with and without arrhythmia detection. The arrhythmia detection algorithm of CASE Cardiac Testing System and CS Cardiac Testing System are provided to the user for the convenience of automatic detection of arrhythmias but does not provide alarms. CASE Cardiac Testing System and CS Cardiac Testing System provide the control of external devices (typically a treadmill or Ergometer) and communicate with centralized electronic/digital storage system via data network. CASE Cardiac Testing System and CS Cardiac Testing System provide a user selectable option for printouts of prognostic scores on select reports. Vector loops are also available. CASE Cardiac Testing System and CS Cardiac Testing System can be configured in a network environment for multiple CASE stations and CS stations allowing the user to create a central database of patient demographics and collected patient physiological data.	CASE V7.0 CARDIAC TESTING SYSTEM, CARDIOSOFT V7.0 CARDIAC TESTING SYSTEM are intended to be used by trained operators under direct supervision of a licensed health care practitioner on adult and pediatric patients. CASE V7.0 CARDIAC TESTING SYSTEM, CARDIOSOFT V7.0 CARDIAC TESTING SYSTEM are designed to acquire, process, record, archive, analyze and output (12 and 15 lead) ECG data during a period of physiologic stress or during a resting ECG test, acquire data from ancillary devices (such as Spirometry and Ambulatory Blood Pressure), provide median morphology recordings and record ECG in real-time with and without arrhythmia detection. The arrhythmia detection algorithm of CASE V7.0 CARDIAC TESTING SYSTEM, CARDIOSOFT V7.0 CARDIAC TESTING SYSTEM are provided to the user for the convenience of automatic detection of arrhythmias but do not provide alarms. CASE V7.0 CARDIAC TESTING SYSTEM, CARDIOSOFT V7.0 CARDIAC TESTING SYSTEM provide the control of external devices (typically a treadmill or Ergometer) and communicate with centralized electronic/digital storage system via data network. CASE V7.0 CARDIAC TESTING SYSTEM, CARDIOSOFT V7.0 CARDIAC TESTING SYSTEM provide a user selectable option for printouts of prognostic scores on select reports. Vector loops are also available. CASE V7.0 CARDIAC TESTING SYSTEM, CARDIOSOFT V7.0 CARDIAC TESTING SYSTEM can be configured in a network environment for multiple CASE and CardioSoft stations allowing the user to create a central database of patient demographics and collected patient physiological data. CASE V7.0 CARDIAC TESTING SYSTEM, CARDIOSOFT V7.0 CARDIAC	Equivalent: The CardioSoft Cardiac Testing System was formerly named CS Cardiac Testing System.

Feature/Function	Predicate Device CASE V6.6 and CS V6.6 (K103678)	Proposed Device CASE V7.0 and CardioSoft V7.0	Explanation of Differences
	CASE Cardiac Testing System and CS Cardiac Testing System are intended to be used primarily in the hospital but can be used in clinics, physician offices, outreach centers or wherever exercise, stress testing, ECG, Spirometry or ambulatory blood pressure testing is performed. CASE Cardiac Testing System and CS Cardiac Testing System offer no diagnostic opinion to the user. Instead, it provides interpretive statements of morphology, rhythm, and conduction for which the physician renders his/her own medical opinion. CASE Cardiac Testing System and CS Cardiac Testing System are not intended to be used as a transport device or for home use. CASE Cardiac Testing System and CS Cardiac Testing System are not intended for the use as a vital signs physiological monitor. CASE Cardiac Testing System and CS Cardiac Testing System are not intended for intracardiac use. CASE Cardiac Testing System and CS Cardiac Testing System are not intended for the use as an emergency device. CASE Cardiac Testing System and CS Cardiac Testing System will not cause abnormal operation of a patient's cardiac pacemaker or other electronic stimulators. CASE Cardiac Testing System and CS Cardiac Testing System are not intended for use with high frequency surgical units. Disconnect the patient from CASE Cardiac Testing System and CS Cardiac Testing System before using the high frequency surgical unit.	TESTING SYSTEM intended to be used primarily in the hospital but can be used in clinics, physician offices, outreach centers or wherever exercise, stress testing, ECG, Spirometry or ambulatory blood pressure testing is performed. CASE V7.0 CARDIAC TESTING SYSTEM, CARDIOSOFT V7.0 CARDIAC TESTING SYSTEM offer no diagnostic opinion to the user. Instead, it provides interpretive statements of morphology, rhythm, and conduction for which the physician renders his/her own medical opinion. CASE V7.0 CARDIAC TESTING SYSTEM, CARDIOSOFT V7.0 CARDIAC TESTING SYSTEM are not intended to be used as a transport device or for home use. CASE V7.0 CARDIAC TESTING SYSTEM, CARDIOSOFT V7.0 CARDIAC TESTING SYSTEM are not intended for use as a vital signs physiological monitor. CASE V7.0 CARDIAC TESTING SYSTEM, CARDIOSOFT V7.0 CARDIAC TESTING SYSTEM are not intended for intracardiac use. CASE V7.0 CARDIAC TESTING SYSTEM, CARDIOSOFT V7.0 CARDIAC TESTING SYSTEM are not intended for use as an emergency device. CASE V7.0 CARDIAC TESTING SYSTEM, CARDIOSOFT V7.0 CARDIAC TESTING SYSTEM will not cause abnormal operation of a patient's cardiac pacemaker or other electronic stimulators. CASE V7.0 CARDIAC TESTING SYSTEM, CARDIOSOFT V7.0 CARDIAC TESTING SYSTEM are not intended for use with high frequency surgical units. Disconnect the patient from CASE V7.0 CARDIAC TESTING SYSTEM, CARDIOSOFT V7.0 CARDIAC TESTING SYSTEM before using the high frequency surgical unit	
Device Type	ECG recording system	ECG recording system	Identical
Modalities	Resting ECG Exercise Test Spirometry Ambulatory Blood Pressure ErgoSpirometry (consists of	Resting ECG Exercise Test Spirometry Ambulatory Blood Pressure	Equivalent Ergospirometry measurement in the Exercise testing, will not

Feature/Function	Predicate Device CASE V6.6 and CS V6.6 (K103678)	Proposed Device CASE V7.0 and CardioSoft V7.0	Explanation of Differences
	Exercise Test and ergospirometry/metabolic test)		be offered for sale with the subject device in US.
Device Description	CASE is a medical cart including a thermal writer. The system cart is based on an embedded PC with CAM 14 acquisition module. The application software is pre-installed. CASE can be configured to maintain a local database or use a shared database on a server. Additional devices like treadmills, ergometers ambulatory blood pressure devices and spirometer devices can be connected. CS utilizes a customer-provided PC and consists of the application software and the CAM USB acquisition module (CAM14 and CAM-USB Interface), which connects to the PC's USB port. CS can be configured to maintain a local database or use a shared database on a server. There are a number of peripheral devices and accessories that can be connected.	CASE is a medical cart including a thermal writer. The system cart is based on an embedded PC with wired acquisition module CAM Connect 14 (CC14) and GEH ECG 1200 wireless acquisition module. The application software is pre-installed. CASE can be configured to maintain a local database or use a shared database on a server. Additional devices like treadmills, ergometers ambulatory blood pressure devices and spirometer devices can be connected. CardioSoft utilizes a customer-provided PC and consists of the application software and acquisition modules (CAM Connect 14, CAM-USB interface, and GEH ECG 1200), which connects to the PC's USB port. CardioSoft can be configured to maintain a local database or use a shared database on a server. There are a number of peripheral devices and accessories that can be connected.	Equivalent The proposed device support both wired (CC-14) and wireless (GEH ECG 1200) ECG acquisition modules which don't impact safety and effectiveness of the device. Refer to section 18 for Performance data
Operating System	CASE: Windows XP embedded CS: Windows XP, Windows XP Pro, Windows Vista Home Premium, Windows Vista Business,	CASE: Windows 10 IoT Enterprise 64 bit CardioSoft: Windows 10 Professional (64 bit) Windows 10 Enterprise (64 bit). Windows Server 2016 (64 bit). Windows Server 2019 (64 bit)	Equivalent Removed old Windows OS due to obsolescence and added current Windows OS to take advantage of current technology operating system.

Feature/Function	Predicate Device CASE V6.6 and CS V6.6 (K103678)	Proposed Device CASE V7.0 and CardioSoft V7.0	Explanation of Differences
Data Management	MUSE Interface Interface to the MUSE Cardiology Information System. Patient Demographics and Orders are imported from MUSE. Exercise Tests, Resting ECGs are exported to MUSE. BDT/GDT Interface Protocol for system-independent data transfer of medical data defined by QMS (Quality association for medical software, Germany) HIS: HL7 EMR interface Interface to Centricity EMR (formally known as Logician) has been added for customer convenience to enter demographic data once and to provide a URL/link to the specific patient record in the CASE/CardioSoft database. Demographic and clinical data import and export to an Electronic Medical Record EMR. EMR Gateway Configurable HL7 Interface outbound only. Demographic and clinical data export to EMR providers based on PDF and XML export. DICOM Interface Protocol for querying and retrieving a DICOM Modality Worklist from a Worklist Service Control Provider (SCP), sending test status to a DICOM Modality Performed Procedure Step SCP, sending storage commitment requests (and receiving replies) to a DICOM Storage	MUSE Interface Interface to the MUSE Cardiology Information System. Patient Demographics and Orders are imported from MUSE. Exercise Tests, Resting ECGs are exported to MUSE. BDT/GDT Interface Protocol for system-independent data transfer of medical data defined by QMS (Quality association for medical software, Germany) DICOM Interface Protocol for querying and retrieving a DICOM Modality Worklist from a Worklist Service Control Provider (SCP), sending test status to a DICOM Modality Performed Procedure Step SCP, sending storage commitment requests (and receiving replies) to a DICOM Storage Commitment SCP, exporting DICOM Composite Instances (ECG Waveforms for Exercise tests and Final report as DICOM Encapsulated PDF for all types of tests) as Storage Service Control User (SCU) and DICOM verification (as SCP & SCU). Introduced DICOM with Encryption (TLS Ver 1.2) DCAR Communication Protocol (DCP with Encryption) Communication with MUSE and EMR Gateway. Database is updated from Btrieve to Microsoft SQL Server	Equivalent Introduced DICOM with Encryption (TLS Ver 1.2) DCAR Communication Protocol (DCP with encryption) is added to improve the efficiency of communication for MUSE interface and EMR gateway. HL7 EMR Communication is not supported with the proposed device.

Feature/Function	Predicate Device CASE V6.6 and CS V6.6 (K103678)	Proposed Device CASE V7.0 and CardioSoft V7.0	Explanation of Differences
	Commitment SCP, exporting DICOM Composite Instances (ECG Waveforms for Exercise tests and Final report as DICOM Encapsulated PDF for all types of tests) as Storage Service Control User (SCU) and DICOM verification (as SCP & SCU).		
Export Formats	Word, Excel, PDF, XML	Word, Excel, PDF, XML	Identical
Archiving	All test data can be stored electronically on hard drive, network server, floppy disk, CD-RW or can be printed out	All test data can be stored electronically on hard drive, network server, external media or can be printed out	Equivalent Removed obsolete storage media (floppy disk,) compared to predicate,
Media Storage Device	• CD Drive R/W • SD Card Reader • Internal storage (Integrated in CASE; available as peripheral for CS)	• CD Drive R/W • SD Card Reader • External storage through USB port • internal storage (available as peripheral for CARDIOSOFT)	Equivalent Removed obsolete storage media (floppy disk,) External storage through USB Port is added
Analog / TTL output ports to interface	• Echocardiographic Devices • Nuclear Cameras	• Echocardiographic Devices • Nuclear Cameras	Identical
Serial I/O ports USB Ports	• Treadmill(Serial) • Ergometer(Serial) • Automated Blood Pressure Units(Serial) • Metabolic Systems • Pulse Oximeters • Spirometer • Ambulatory Blood Pressure Device	• Treadmill(Serial/USB) • Ergometer(Serial/USB) • Automated Blood Pressure Units (Serial/USB) • Metabolic Systems • Pulse Oximeters • Spirometer • Ambulatory Blood Pressure Device	Equivalent: Added support for USB ports to take advantage of current technology.
ECG Modality			
ECG Acquisition Module	CS: CAM-USB acquisition module (CAM14 and CAM-USB Interface) CAM-USB A/T CASE: CAM14	CardioSoft : CAM Connect 14 (CC14), and GEH ECG 1200 wireless acquisition module (cleared under K080141) CASE: CAM Connect 14 (CC14)and GEH ECG 1200	Equivalent: The proposed device will have both wired and wireless acquisition modules.

Feature/Function	Predicate Device CASE V6.6 and CS V6.6 (K103678)	Proposed Device CASE V7.0 and CardioSoft V7.0	Explanation of Differences
		Wireless acquisition module (Cleared under K080141).	
BP Devices	Measurement is triggered, systolic and diastolic BP value read from device.	Measurement is triggered, systolic and diastolic BP value read from device.	Identical
SPO2 Devices (exercise test only)	SPO2 value is read from the devic	SPO2 value is read from the device	Identical
Ergometers (exercise test only)	Load value is sent to ergometer Actual load value and revolutions are read from ergometer	Load value is sent to ergometer Actual load value and revolutions are read from ergometer	Identical
Treadmills (exercise test only)	Treadmill is started and stopped. Speed and Grade value is sent to Treadmill. Actual Speed and Grade value is read from treadmill.	Treadmill is started and stopped. Speed and Grade value is sent to Treadmill. Actual Speed and Grade value is read from treadmill.	Identical
Spirometry Module	SpiroSoft (K031194) and EasyOne-CS (K993921)	Spiro-SP TrueFlow Sensor at Easy on-PC (K090034)	Equivalent The proposed device will support cleared module Spiro-SP TrueFlow Sensor at Easy on-PC (K090034)
ABP Module	Tonoport V (K012647)	Tonoport V (K012647) Tonoport VI (K170966)	Equivalent The proposed device will support a cleared module Tonoport VI (K170966)
ECG System Performance			
Leads/Channels Resting ECG	12, 15	12, 15	Identical
Leads/Channels Stress Test	3, 6, 12, 15	3, 6, 12, 15	Identical
Paper speed - Thermal Writer	25, 50 mm/s +/- 2% 5, 12.5 mm/s +/- 10%	25, 50 mm/s +/- 2% 5, 12.5 mm/s +/- 10%	Identical
Frequency Response	3dB, display and writer	3dB, display and writer	Identical
ECG Signal Bandwidth	0.01 to 150 Hz (CAM 14)	0.04 to 150 Hz (CC14). Note: CC 14 is cleared with MAC VU 360 (K173830)	Equivalent ECG Bandwidth as per the IEC60601-2-25 standard is 0.67 Hz to 150 Hz which is well within the bandwidth of 0.04 Hz. Therefore there is no loss

Feature/Function	Predicate Device CASE V6.6 and CS V6.6 (K103678)	Proposed Device CASE V7.0 and CardioSoft V7.0	Explanation of Differences
			of ECG Data even if the bandwidth is 0.04 Hz
Sensitivity	2.5/5/10/20 mm/mV	2.5/5/10/20 mm/mV	Identical
Online ECG (Full disclosure)	In the operation mode "stress test" the ECG can be stored electronically. Alternatively selected segments of the ECG can be printed out. Online ECG (full disclosure) for "resting ECG"	In the operation mode "stress test" the ECG can be stored electronically. Alternatively selected segments of the ECG can be printed out. Online ECG (full disclosure) for "resting ECG"	Identical
Sample Rate	Sample rate at point of analysis is 500 Hz.	Sample rate at point of analysis is 500 Hz.	Identical
Noise	< 15uV p-p RTI <2.5uV RMS IEC/AHA recommendation	< 15uV p-p RTI <2.5uV RMS IEC/AHA recommendation	Identical
ECG Signal Input for Resting and Stress ECG			
Electrode connections	IEC: R, L, F, N, C1-C6 AHA: RL, RA, LL, LA, V1-V6 Supported also: - V3r, V4r, V5r, V7-V9, A1-A4 - CMH, CML, NEHB electrode sets - Option to acquire additional 4 uni-polar leads simultaneously	IEC: R, L, F, N, C1-C6 AHA: RL, RA, LL, LA, V1-V6 Supported also: - V3r, V4r, V5r, V7-V9, A1-A4 - CMH, CML, NEHB electrode sets - Option to acquire additional 4 uni-polar leads simultaneously	Identical
Electrodes monitored for disconnection	Every electrode except RL	Every electrode except RL	Identical
Detection of pacemaker pulse	CAM 14: >750 uV @ 50 uS	CC14: Duration: 0.1 ms to 2.2 ms Amplitude: 2 mV to 700 mV Separation: 1 ms or greater	Equivalent CC 14 complies to the clause no 201.12.4.109 of IEC 60601-2-25 :2011. CC 14 is cleared with MAC VU 360 (K173830)

Feature/Function	Predicate Device CASE V6.6 and CS V6.6 (K103678)	Proposed Device CASE V7.0 and CardioSoft V7.0	Explanation of Differences
Input impedance for differential signals at 10 Hz	CAM14: >10 M Ohm	CC14: >2.5M Ohm	Equivalent IEC 60601-2-25:2011 requirement is that the Input impedance is minimum 2.5 M Ohms. CC 14 complies to this requirement. CC 14 is cleared under K173830
Input impedance for common-mode signals at 60Hz	>50 M Ohm	>50 M Ohm	Identical
Common mode rejection ratio	> 140 dB > 123 dB with AC filter enabled	> 140 dB > 123 dB with AC filter enabled	Identical
Dynamic range at AC voltage	+/- 320 mV +/- 10 mV	+/- 300 mV +/- 5 mV	Equivalent IEC 60601-2-25:2011 requirement is that Offset shall be +/- 300mV DC and AC Differential Voltage as +/- 5 mV
Patient leakage current	< 5uA normal conditions <10uA single fault condition	< 10 uA normal conditions < 50uA single fault condition	Equivalent IEC 60601-2-25:2011 requirement is that Patient leakage current shall be less than 10 uA in Normal Condition and Less than 50 uA in Single Fault Condition
Line Filter	50 or 60Hz notch filter (selectable)	50 or 60Hz notch filter (selectable)	Identical
High Pass Filter	CAM14: .01 Hz (or .05Hz special use) with DC offset control	CC14: 0.04 Hz	Equivalent: As per IEC 60601-2-25: 2011. the frequency bandwidth shall be 0.67 Hz T0 150 HZ. Having a

Feature/Function	Predicate Device CASE V6.6 and CS V6.6 (K103678)	Proposed Device CASE V7.0 and CardioSoft V7.0	Explanation of Differences
			bandwidth of 0.04 Hz to 150 HZ will accommodate all the useful information of ECG.
Inputs: Patient Demographics, Non-ECG Data			
Stress Protocols	Treadmill: BRUCE, MODBRUCE, NAUGHTON, ELLESTAD, MODBALKE, USAFSAM, SLOWUSAFSAM, CORNELL, BALKEWARE, MODBALKEWARE, ADENOSIN, DOBUTAMINE, PERSANTINE, User defined Ergometer: WHO, WHO50, WHO75, HOLLMANN, BAL, STD. FRANCE, MODWHO, CONCONI, User defined	Treadmill: BRUCE, MODBRUCE, NAUGHTON, ELLESTAD, MODBALKE, USAFSAM, SLOWUSAFSAM, CORNELL, BALKEWARE, MODBALKEWARE, ADENOSIN, DOBUTAMINE, PERSANTINE, User defined Ergometer: WHO, WHO50, WHO75, HOLLMANN, BAL, STD. FRANCE, MODWHO, CONCONI, User defined	Identical
Exercise parameters	Time: phase, stage, clocks Treadmill: Speed(mph,km/h), grade Pharma stress: Drug/dosage, Bike: weight (kg), load (Watts) Metabolic Equivalent Measurement (METs) Other derivatives: exercise time, workload	Time: phase, stage, clocks Treadmill: Speed(mph,km/h), grade Pharma stress: Drug/dosage, Bike: weight (kg), load (Watts) Metabolic Equivalent Measurement (METs) Other derivatives: exercise time, workload	Identical
Blood Pressure	Systolic / Diastolic (mmHg, kPa) is manually entered or automatically acquired by the proposed device.	Systolic / Diastolic (mmHg, kPa) is manually entered or automatically acquired by the proposed device.	Identical

Feature/Function	Predicate Device CASE V6.6 and CS V6.6 (K103678)	Proposed Device CASE V7.0 and CardioSoft V7.0	Explanation of Differences
Patient demographics	Yes	Yes. Visit number and Secondary Patient ID is added	Equivalent. Visit number and Secondary Patient ID Demographics fields are added based on customer request.
Indication of Detected Pacemaker pulses	Pacemaker activity identified by ECG acquisition hardware. Leveraging newer technology for pacemaker detection improvements	Pacemaker activity identified by ECG acquisition hardware. Leveraging newer technology for pacemaker detection improvements	Identical
ECG - Arrhythmia Features			
Arrhythmia Detection during exercise test	Yes	Yes	Identical
Arrhythmia detection in Resting RCG/ Full disclosure	Yes	Yes	Identical
Arrhythmia Annotation	ASYSTO, CPLT, ESC, L, PAU1, PAU2, PCAP, PERR, QRSL, RUN, SVPB, VBIG, VIFB, VPB, VTAC	ASYSTO, CPLT, ESC, L, PAU1, PAU2, PCAP, PERR, QRSL, RUN, SVPB, VBIG, VIFB, VPB, VTAC	Identical

HEART exercise / ECG interpretation	HEART exercise (K091594)	HEART exercise (K091594)	Identical
Resting ECG - Processing Data			
ECG Analysis/ Interpretation (12SL)	12SL ECG Analysis Program (V21) (K060833)	12SL ECG Analysis Program (V23) (K141963)	Equivalent Implementing 12SL v23 cleared under K141963
Resting ECG Re-analysis	Manual setting of measurement points	Manual setting of measurement points	Identical
Automatic baseline correction	Yes	Yes	Identical
Resting ECG - Measured Parameters			
Intervals	12SL global: PR, QRS, QT, QTC, P, RR, PP 12SL lead dep.: QD, RD, SD, RPD HEART global: PR, QRS, QT, QTC, P, RR, PP, QTD, QTcBD HEART lead dep.: Q, R, S, Rp, QT	12SL global: PR, QRS, QT, QTC, P, RR, PP 12SL lead dep.: QD, RD, SD, RPD HEART global: PR, QRS, QT, QTC, P, RR, PP, QTD, QTcBD HEART lead dep.: Q, R, S, Rp, QT	Identical
Amplitudes	12SL lead dep: PA, PPA QA, RA, SA, RPA TA TPA HEART lead dep.: P, Q, R, S, R', S', J, ST, T	12SL lead dep: PA, PPA QA, RA, SA, RPA TA TPA HEART lead dep.: P, Q, R, S, R', S', J, ST, T	Identical
hers	P-R-T axes Heart Rate ST slope	P-R-T axes Heart Rate ST slope	Identical
Interpretation	12SL Diagnosis HEART Diagnosis ACI-Tipi Diagnosis (K9974199)	12SL Diagnosis HEART Diagnosis ACI-Tipi Diagnosis (K9974199)	Identical
Resting ECG - Display			
ECG Traces	12 or 15	12 or 15	Identical
ECG Speed	25/50 mm/sec.	25/50 mm/sec.	Identical
ECG Display	Test Summary (Patient Information, Global Measurement Results, Test information, Interpretation)	Test Summary (Patient Information, Global Measurement Results, Test information, Interpretation)	Identical

	ECG Traces Medians Lead dependent Measurement Results Arrhythmia Review Vector Loops Full Disclosure ECG	ECG Traces Medians Lead dependent Measurement Results Arrhythmia Review Vector Loops Full Disclosure ECG	
Print Formats	Configured Reports Standard Reports Medians Vector Loops Full Disclosure ECG Rhythm Report	Configured Reports Standard Reports Medians Vector Loops Full Disclosure ECG Rhythm Report	Identical
Colored Reports	YES	YES	Identical
Previous Test Report Retrieval	Simultaneous previous report review capability in post test review mode	Simultaneous previous report review capability in post test review mode	Identical
Manual ECG measurement	Yes, paper and on screen	Yes, paper and on screen	Identical
Exercise ECG - Display			
ECG Traces	Maximum 15 traces in one screen	Maximum 15 traces in one screen	Identical
Exercise Test Assessment	Visual Assessment of ECG Traces CS: Audio Assessment of ECG Traces	Visual Assessment of ECG Traces CardioSoft: Audio Assessment of ECG Traces	Identical
Sweep Speed	25/50 mm/sec.	25/50 mm/sec.	Identical
Display Data	Heart Rate (HR) Target HR Max predicted HR Clocks (stress test) Blood Pressure (BP [mmHg,kPa]) Rate Pressure Product (RPP) Avg. beat w/ST fiducial points Protocol Stage Protocol Phase Protocol Name Treadmill Speed and Grade METS display Spirometer measurement SpO2 Target Load Ergometer Load/RPM Quantitative Lead Prep. Measurements Arrhythmia Display HR recovery HR reserved used FVE recovery	Heart Rate (HR) Target HR Max predicted HR Clocks (stress test) Blood Pressure (BP [mmHg,kPa]) Rate Pressure Product (RPP) Avg. beat w/ST fiducial points Protocol Stage Protocol Phase Protocol Name Treadmill Speed and Grade METS display Spirometer measurement SpO2 Target Load Ergometer Load/RPM Quantitative Lead Prep. Measurements Arrhythmia Display HR recovery HR reserved used FVE recovery	Identical
Trends	Heart rate Blood Pressure	Heart rate Blood Pressure	Identical

	Speed Grade ST-level ST-slope. User definable, also including double product: RPP ST Integral Pulse Rate Respiratory Rate Tidal Volume ST-HR Loops PVC/min Exertion Scale Exercise Time Workload J Level J+20 Level J+60 Level ST/HR slope ST/HR index (ST vs. HR) SpO2 V O2 VC O2 ETC O2 Cardiac Output TWA METS VE/min ST/HR hysteresis	Speed Grade ST-level ST-slope. User definable, also including double product: RPP ST Integral Pulse Rate Respiratory Rate Tidal Volume ST-HR Loops PVC/min Exertion Scale Exercise Time Workload J Level J+20 Level J+60 Level ST/HR slope ST/HR index (ST vs. HR) SpO2 V O2 VC O2 ETC O2 Cardiac Output TWA METS VE/min ST/HR hysteresis	
ECG Display/Print Formats	Medians Linked Medians Recall Reports Tabular Summary Reports Sample cardiac cycle reports 3/6/12/15-Lead reports Graded exercise summary report Waterfall display TWA medians Trends Reports 12SL Report Vector Loops Rhythm Report Full disclosure (in Post test)	Medians Linked Medians Recall Reports Tabular Summary Reports Sample cardiac cycle reports 3/6/12/15-Lead reports Graded exercise summary report Waterfall display TWA medians TWA full disclosure Trends Reports 12SL Report Vector Loops Rhythm Report	Equivalent Full disclosure was available in Post test and is now available during acquisition and in Post test
Previous Test Report Retrieval	Simultaneous previous report review capability during current test.	Simultaneous previous report review capability during current test.	Identical
Manual ECG measurement	Yes, paper and on screen	Yes, paper and on screen	Identical

Performance standards:	The CASE V7.0 and CardioSoft V7.0 complies with the voluntary consensus standard ANSI/AAMI ES60601-1:2005/(R)2012 and its relevant collateral and particular standards.
Determination of Substantial Equivalence: tested	Summary of Non-Clinical Tests The CASE V7.0 & Cardiosoft V7.0 program was designed and for compliance with applicable clauses of the following voluntary standard: IEC 60601-2-25 : 2011– Medical Electrical Equipment – Part 2-25 Particular requirements for the Basic Safety and Essential performance of Electrocardiographs The following quality assurance measures were applied to the development of the system: - Risk Analysis - Requirements Reviews - Verification Testing - Performance testing - EMI-EMC & Safety Testing - Summary of Clinical Tests:
Summary of Clinical Tests:	The subject of this premarket submission, CASE V7.0 and CardioSoft V7.0 did not require clinical studies to support substantial equivalence.
Conclusion:	The CASE V7.0 and CardioSoft V7.0 to be as safe, as effective, and performance is substantially equivalent to the predicate device.