DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 28, 2017

Medtronic, Inc.
Laura Danielson
Principal Regulatory Affairs Specialist
8200 Coral Sea Street Ne
Mounds View, Minnesota 55112

Re: K163008
Trade/Device Name: Carelink SmartSync Device Manager Pacing System Analyzer
Regulation Number: 21 CFR 870.3605
Regulation Name: Pacing System Analyzer
Regulatory Class: Class II
Product Code: DTA, DTE
Dated: January 25, 2017
Received: January 26, 2017

Dear Laura Danielson:

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. 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.

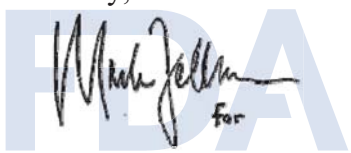
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163008

Device Name
Carelink SmartSync Device Manager Pacing System Analyzer

Indications for Use *(Describe)*
The base is intended to be used as part of the CareLink SmartSync device manager system. Clinicians use the base to analyze the electrical performance of cardiac leads during device implant or invasive troubleshooting. Clinicians use the base's ECG connections along with the app display to view, measure, and record live cardiac waveforms. The base is intended to be used by healthcare professionals only in operating environments under direct medical supervision.

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

Date Prepared:	January 13, 2017
510(k) Owner / Address:	Medtronic, Inc. Cardiac Rhythm and Heart Failure 8200 Coral Sea Street Mounds View, MN 55112
Contact:	Laura L. Danielson Principal Regulatory Affairs Specialist
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Trade / Proprietary Name:	CareLink SmartSync™ Device Manager Pacing System Analyzer
Common Name:	Pacing System Analyzer
Classification / Classification Name:	Class II Pacing System Analyzer (21 CFR 870.3605)
Product Code:	DTA, DTE

Predicate Devices

The intended use, design, materials and performance of the CareLink SmartSync™ Device Manager Pacing System Analyzer with associated Applications (Models: D00U001, D00U002, M01G02, M01A02, M01G01, and M01A01), cables (previously approved) and accessories are substantially equivalent to the following predicate device:

- Medtronic Model 2290 Lead Analyzer approved on 13MAR2002 P890003/S065.
- Medtronic Model 5311B A-V Pacing System Analyzer cleared on 07MAY1991 K910595.

Device Description

Device Identification:

The following is a list all key device components included in the submission:

- CareLink SmartSync Device Manager base (PSA hardware), Model 24970A
- CareLink SmartSync PSA App, Model D00U002
- CareLink SmartSync Host, Model D00U001

- CareLink SmartSync Common Application, Model M01G02 (Android) and Model M01A02 (iOS)
- CareLink SmartSync Platform, Model M01G01 (Android) and Model M01A01 (iOS)
- Non-Medical Mobile Platform (i.e. Tablet)

The following compatible accessories are available for the CareLink SmartSync Device Manager base (PSA hardware) that Medtronic is seeking clearance for in this 510(k) submission:

- ME20A054F03 power supply (Medtronic re-order number: 249701), 1.8 m (approximately 6 ft.): a floor mount that connects through the 249705 AC power cord to the wall on one end, and through a DC power cord to the base station on the other end with a right angle barrel plug
- 249705 AC power cord, 1.8 m (approximately 6 ft.): Connects the power supply to AC power
- 249702 USB cable, approximately 3 m (10 ft.): connects to the Model 24967 patient connector (not the subject of this submission, but in another 510(k) but only upon approval of both models)
- 249672 Tether Kit: Secures the USB cable 249702 and Power supply 24951 to the Model 24967 patient connector (Not the subject of this 510(k) submission). Contains an Allen wrench, screw, and cable retainer
- 249703 Wall mount: mounts the base to the wall when table space is a concern

The above listed accessories are considered **off the shelf** and **non-medical**.

The following compatible cables and adaptors are available for the base. These are the same adaptors and cables used with the current market approved and released Model 2290 PSA predicate and are considered medical devices.

Surgical and patient cables connect the base to cardiac leads for lead analysis. Adaptors allow surgical and patient cables to be connected to the base when their plugs are not compatible with the Type CF connection port on the base. Ground cables connect to the base (via alligator clip connecting to a cable) and complete the electrical circuit when connected to unipolar implantable cardiac device leads.

- 2292 Surgical cable, 3.66 m (12 ft.) – Approved: P890003/S065, 13MAR2002
- 5103 A/V adaptor – Approved: P890003/S054, 24SEPT1998
- 5104 Analyzer Adaptor – Approved: P890003/S054, 24SEPT1998
- 5114 Adaptor – Approved P890003 (initial submission), 24AUG1989
- 5832 Surgical cable, approximately 3.5 m (12 ft.) – P890003/S070, 31OCT1995
- 5833S Surgical cable, 1.83 m (6 ft.) – Cleared: K923407, 19OCT1992
- 5833SL Surgical cable, 3.66 m (12 ft.) – Cleared: K923407, 19OCT1992
- 5473 Ground cable - Cleared: K961520, 13NOV1996
- 5436 Analyzer patient cable, 3.66 m (12 ft.) – Approved: P890003/S054, 24SEPT1998

The following compatible ECG interface cables, ECG cables, and adaptors are available for the base. These are the same Adaptors and Cables used with the current market approved and released Model 2290 PSA predicate and are considered medical devices.

ECG cables and leads connect the base to surface electrodes on the patient for the display of live waveforms. Adaptors allow ECG monitors with phono connectors to be connected to the base.

- 5437 ECG Interface cable, 6.4 m (20 ft.) – Approved: P890003/S065, 13MAR2002
- 5437A Adaptor – Approved: P890003/S065, 13MAR2002
- 2090EC ECG cable, approximately 2.6 m (103 in.) – Approved: P890003/S065, 13MAR2002
- 2090ECL ECG cable, approximately 5.5 m (215 in.) – Approved: P890003/S065, 13MAR2002
- 9790LA ECG leads, approximately 1 m (40 in.) – Approved: P890003/S027, 29NOV1994
- 9790XLA ECG leads, approximately 1 m (40 in.) – Approved: P890003/S027, 29NOV1994

Medtronic recommends the use of Medtronic-supplied components only. Use of unapproved components may reduce device effectiveness or impact user or patient safety.

Device Characteristics:

The CareLink SmartSync PSA is comprised of Base, software applications, associated cables and power cords. The software applications reside on a mobile platform or tablet and pair via Bluetooth® with the base hardware. The mobile platform is considered non-medical. The Operating System is also non-medical software that is delivered with and resides on the Mobile Platform.

The CareLink SmartSync Device Manager base (Model 24970A) is not considered a single-use device.

The CareLink SmartSync Device Manager base (Model 24970A) is not provided sterile.

Environment of Use:

The base is intended to be used by healthcare professionals only in operating environments under direct medical supervision.

Brief Written Description of the Device:

The CareLink SmartSync Device Manager system (referred to from now on as the device manager system) is comprised of the Model 24970A Base and CareLink SmartSync Device Manager app installed and running on your mobile device.

The CareLink SmartSync Device Manager Base (referred to from now on as the base) pairs with the Medtronic CareLink SmartSync Device Manager app on your mobile device to analyze the cardiac lead system for an implantable Medtronic device. The base includes these features:

- Analyzer hardware and patient cable connections to support electrical assessment of cardiac leads during implant.

- ECG cable connections to collect live cardiac waveform data that can be viewed, measured, and recorded using the app running on your mobile device.
- Bluetooth® wireless technology to communicate with the app running on your mobile device.1

The Model 24970A Base contains a microprocessor that maintains the pacing engine logic function for the PSA.

The PSA hardware within the Base consists of two main integrated circuits (ICs) which provide a variety of functions as listed below:

- Micro Controller Unit: the microprocessor is used to provide timing support and also onboard memory for the device.
- Mixed Signal Integrated Circuit: the mixed signal IC chip takes the input signals from the cables (connected to a lead) and digitizes it for use by the device. This IC is also responsible for the electrogram (EGM) waveform and power management.

The App is the primary user interface for the device manager system. The App for the CareLink SmartSync PSA is comprised of four main components:

- A **Host Application** component that provides the system user interface necessary to initialize, and set-up the CareLink SmartSync Device Manager and launch the PSA Clinician Application
- a **Platform Application** component for the transfer/exchange, storage/retrieval, electronic conversion, and electronic display of medical device data
- a **Common Application** component that is a collection of software components that are utilized by the PSA or Device Applications
- a **PSA Application** component that is a Mobile Platform Application that allows user to use the PSA device

The App includes these features:

- Bluetooth® connectivity to pair with the base.
- Integration with the base to start a lead analysis session.
- Mobile device connectivity tools for sharing and printing Analyzer reports.
- Updates to app software using an Internet connection.

The Analyzer tools in the App form the primary user interface to the Base). These tools display and report on the cardiac lead and ECG data transmitted from the base. Clinicians use this data to perform these tasks:

- Analyze electrical performance of cardiac leads during implant.
- Assess proper placement of cardiac leads during implant.
- View, measure, and document live cardiac waveforms.

CareLink SmartSync Application Models installed on a clinician’s off-the-shelf non-medical mobile device. The Operating System is also non-medical software that is delivered with and resides on the non-medical Mobile Platform.

The Analyzer has the following features:

- Dual and single chamber pacing modes.
- Automatic measurement of P-wave and R-wave amplitudes.
- Lead impedance measurement.
- Real-time display of atrial and ventricular EGM and ECG waveforms.
- Rapid atrial stimulation to 850 min−1 (ppm).
- Advanced pulse width versus amplitude pacing threshold tests.
- Measurement reports.

The CareLink SmartSync Device Manager provides the essential capabilities for analysis of and the electrical performance of cardiac leads during device implant in a hospital environment (See **Tables 1** through **Table 4**).

Table 1: PSA Base Physical Characteristics

Parameter	Value
Footprint	548 cm^2
Mass	0.91 kg (2.0 lbs.)
Dimensions H x W x D	1.8 in x 9.45 in x 8.2 in
Device identification code	Device serial number prefix "SPM"
Power Source	5V Direct Current provided by Medical Grade External Power Supply. PSA Battery info in the following table.

Table 2: PSA Base (off the shelf) AA Battery Characteristics

Parameter	Value
Manufacturer	Panasonic
Model/type	IEC LR6 Alkaline Battery (AA) (n=2) per Base
Chemistry	Alkaline
Battery Life dependence upon utilization monitored by the Mobile Application on the user mobile device.	2 years required replacement as indicated by the Maintenance schedule

Table 3: PSA Base ECG Signal Characteristics

Parameter	Description	Fixed Value
ECG Gain	Surface ECG User Interface display	1.0
Sampling Rate	Rate at which the ECG signal is digitized	500 Hz
Sampling Resolution	Number of bits per sample used in the digitization of the ECG signal	16 bits / sample

Table 4: PSA Base EGM Signal Characteristics

Parameter	Description	Fixed Value
EGM Gain, Atrial	Amplification of the atrial EGM signal	75X
EGM Gain, Ventricular	Amplification of the ventricular EGM signal	18.75X
High Pass Pole	-3dB high pass filter frequency	2.0Hz to 3.0Hz
Low Pass Pole	-3dB low pass filter frequency	80Hz to 110Hz
Sampling Rate	Rate at which the EGM signal is digitized	256 Hz
Sampling Resolution	Number of bits per sample used in the digitization of the EGM signal	8 bits / sample

Materials of Use

The following is a list of exposed materials included in the manufacture of the Model 24970A:

Component	Material
Top Enclosure Base	**Plastic:** SABIC LEXAN EXL-9330 Polycarbonate White Resin per Medtronic color chip M954239A001 **Elastomer Edge:** Eraprene A6060N-SP Thermoplastic Elastomer Blue per Pantone 301
Lid Base	**Plastic:** SABIC LEXAN EXL-9330 Polycarbonate White Resin per Medtronic color chip M954239A001 **Graphics:** Pantone 301 Blue **Elastomer Edge:** Eraprene A6060N-SP Thermoplastic Elastomer Blue per Pantone 301
Bottom Enclosure Base	**Plastic:** SABIC LEXAN EXL-9330 Polycarbonate White Resin per Medtronic color chip M954239A001 **Graphics:** Pantone 301 Blue
Membrane Keypad Base	**Graphics:** Autotex-2(V200) Polyester **Button:** Silicone Rubber 60 Shore A Clear **Top Coat:** Polyurethane Per color chip Pantone Cool Grey 8

Component	Material
Battery Cover Base	SABIC LEXAN EXL-9330 Polycarbonate White Resin per Medtronic color chip M954239A001
Foot Rear Base	Silicone Rubber 70 Shore A Color: Pantone Cool Grey 8
Device Label Base	Lexan PC 8B35 Polycarbonate Clear
QR Code Label Base	Lexan PC 8B35 Polycarbonate Clear
PSA Connector Base	Hypertronics D02 Housing Polyethermide Black

The device does not include biologics, drugs, or coating additives. The pacing system analyzer is not intended for patient contact.

Key Performance Specifications/Characteristics of the Device

Base Specifications

Standards (The base complies with the following:)	
Radio frequency wireless specifications and applicable standards	
EMC	EN / IEC 60601-1-2 EN 300 328 EN 301 489 EN 302 195 EN 301 839 EN 55011 Class A
Radio	FCC CFR 47
Patient safety	UL/CUL 60601-1, Type BF applied part, Type CF applied part[a] EN 60601-1, Class 2, continuous operation, Type BF, Type CF[a]
AC power requirement	
Voltage Frequency	100–240 VAC nominal 50/60 Hz nominal
Battery	
Type Voltage	AA Alkaline (LR6) or Lithium-ion, non-rechargeable (quantity of 2) 1.5 V each
Base Electrical Specifications	
Power Supply	
Model Voltage in Voltage out	ME20A0540F03 power supply (Medtronic re-order number 249701) 100-240 VAC 0.5A at 50-60 Hz 5 VDC 3 A
USB Cable	

Model Voltage Power	249702 USB cable 5 V 0.8 A 4 W
Charge cradle	
Model Voltage Power	24970A 5 V 0.8 A 4 W
IEC 60529 Degrees of Protection Provided by Enclosures (IP Code)	
Ingress	This product complies with international electrical safety rating IP2X with regard to ingress of dust, other foreign objects, and water as required by IEC 60601-1.
Physical dimension and weight	
Height Width Depth Weight	4.6 cm (1.8in) 24 cm (9.5 in) 20.8 cm (8.2 in) 0.91 kg (2 lbs)
Temperature Limits	
Operating Storage Transport	10°C to 35°C (50°F to 95°F) 15°C to 30°C (59°F to 86°F) - 30°C to 55°C (-22°F to 131°F)
Humidity Limits	
Operating Storage Transport	8%-80% 15%-93% at 35°C (95°F 15%-93% at 35°C (95°F)
Altitude	
Maximum	3000 m
Connectivity	
Conexus wireless telemetry	
Frequency range Modulation frequency Output power	402-405 MHz Frequency shift key 25 µW EIRP max
Bluetooth 2.1 and 4.0	
Frequency range Modulation frequency Output power	2.4-2.483 GHz Gaussian frequency shift key Less than 10 mW EIRP
[a] The ECG cable (Type BF), 24967 Patient Connector (Type BF) and patient or surgical cable (Type CF) are the only accessories that come into direct contact with the patient. The base itself is not intended to come into contact with the patient during normal use.	
Expected Service Life: 5 years	
Disposal of the base: Return the base to Medtronic for proper disposal. Contact Medtronic at the address or telephone number on the back cover for information on returning the base.	
Electromagnetic compatibility declaration	
The following list of accessories is compliant with the requirements of IEC 60601-1-2.	
Accessory	**Maximum length**

ME20A0540F03 Power supply	1.8 m (6 ft)
249705 AC power cord	1.8 m (6 ft)
249702 USB cable	3 m (10 ft)
24967 Patient Connector	N/A
2292 Surgical cable	3.66 m (12 ft)
5832 Surgical cable	3.5 m (12 ft)
5833S Surgical cable	1.83 m (6 ft)
5833SL Surgical cable	3.66 m (12 ft)
5346 Analyzer patient cable	3.66 m (12 ft)
5437 ECG Interface cable	6.4 m (20 ft)
2090EC EKG cable	2.6 m (103 in)
2090ECL EKG cable	5.5 m (215 in)
9790LA EKG leads	1 m (40 in)
9790XLA EKG leads	1 m (40 in)

Use of accessories other than what is specifically listed may result in increased emissions or decreased immunity of the 24970A base.

The 24970A base needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and used according to the EMC information provided in the accompanying documents.

The 24970A base should not be used adjacent to or stacked with other equipment that is not part of the device manager system (base, mobile device, and accompanying accessories). If adjacent or stacked use is necessary, the 24970A base should be observed to verify normal operation in the configuration in which it will be used.

The 24970A base contains RF transmission and receiving capabilities. Consequently, it is possible that other equipment may interfere with the 24970A base even if that other equipment complies with CISPR emission requirements. The following is a technical summary of the RF communication properties:

Transmitting and receiving:

- Technology type: Conexus wireless telemetry, Bluetooth wireless technology
- Frequency of operation: 402 MHz to 405 MHz, 2.4 GHz to 2.483 GHz
- Modulation characteristics: Frequency shift key, Gaussian frequency shift key
- Field strength: 25 µW EIRP max, less than 10 mW EIRP

Guidance and manufacturer's declaration—electromagnetic emissions

The 24970A base is intended for use in the electromagnetic environment specified below. The customer or the user of the 24970A base should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment—guidance
RF emissions CISPR 11	Group 1	The 24970A base uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Class A	The 24970A base is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplied buildings used for domestic purposes, provided the following warning is heeded: **Warning:** This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the 24970A base or shielding the location.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration—electromagnetic immunity

The 24970A base is intended for use in the electromagnetic environment specified below. The customer or the user of the 24970A base should assure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment—guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential Mode ±2 kV common mode	±1 kV differential Mode ±2 kV common mode	
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% *U*T (>95% dip in *U*T) for 0.5 cycle 40% *U*T (60% dip in *U*T) for 5 cycles 70% *U*T (30% dip in *U*T) for 25 cycles <5% *U*T (>95% dip in *U*T) for 5 s	<5% *U*T (>95% dip in *U*T) for 0.5 cycle 40% *U*T (60% dip in *U*T) for 5 cycles 70% *U*T (30% dip in *U*T) for 25 cycles <5% *U*T (>95% dip in *U*T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the 24970A base requires continued operation during power mains interruptions, it is recommended that the 24970A base be powered from an uninterruptible power supply or a battery. **Note:** *U*T is the AC mains voltage prior to application of the test level.
Power frequency (50/60 Hz) magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 V_{RMS} (volts root-meansquare) 150 kHz to 80 MHz	10 V	Portable and mobile RF communications equipment should be used no closer to any part of the 24970A base, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 0.35\sqrt{P}$

Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m	$d = 0.35\sqrt{P}$ for 80 MHz to 800 MHz $d = 0.70\sqrt{P}$ for 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, consider an electromagnetic site survey. If the measured field strength in the location in which the 24970A base is used exceeds the applicable RF compliance level above, observe the 24970A base to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the 24970A base.
[b] Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the 24970A base

The 24970A base is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the 24970A base can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 24970A base as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	**Separation distance according to frequency of transmitter**		
	150 kHz to 80 MHz $d = 0.35\sqrt{P}$	**80 MHz to 800 MHz** $d = 0.35\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 0.70\sqrt{P}$
0.01 W	0.035 m	0.035 m	0.070 m
0.1 W	0.11 m	0.11 m	0.22 m
1 W	0.35 m	0.35 m	0.70 m
10 W	1.1 m	1.1 m	2.0 m
100 W	3.5 m	3.5 m	7.0 m

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Indications for Use

The following is the Indications for Use Statement:

The base is intended to be used as part of the CareLink SmartSync device manager system. Clinicians use the base to analyze the electrical performance of cardiac leads during device implant or invasive troubleshooting. Clinicians use the base's ECG connections along with the app display to view, measure, and record live cardiac waveforms.

The base is intended to be used by healthcare professionals only in operating environments under direct medical supervision.

Comparison of Technological Characteristics with the Predicate Device

The following table contains a comparison of the CareLink SmartSync Device Manager Pacing System Analyzer to the predicate devices (Models 2290 and 5311B).

Device Parameter	CareLink SmartSync™ Device Manager (Model 24970A) and Applications (D00U002, D00U001, M01G02, M01A02, M01G01, and M01A01) KXXXXXX	Medtronic Pacing System Analyzer (Model 2290) P890003/S065	Medtronic A-V Pacing System Analyzer (Model 5311B) K910595 07MAY1991	Primary Predicate	Difference
Classification Name	Analyzer Lead Analysis Device  Class II	Analyzer Lead Analysis Device  Class III	AV pacing System Analyzer  Class III	Medtronic Pacing System Analyzer Model 2290	Same

Device Parameter	CareLink SmartSync™ Device Manager (Model 24970A) and Applications (D00U002, D00U001, M01G02, M01A02, M01G01, and M01A01) KXXXXXX	Medtronic Pacing System Analyzer (Model 2290) P890003/S065	Medtronic A-V Pacing System Analyzer (Model 5311B) K910595 07MAY1991	Primary Predicate	Difference
General Description	The CareLink SmartSync Device Manager is a microprocessor-based Device. The device is designed to **analyze the electrical performance of a cardiac lead system**, using the mobile device platform and associated applications as a control and display platform.	The Analyzer is a microprocessor-based accessory that installs into the programmer. **The Analyzer is designed to analyze the electrical performance of a cardiac lead system, and uses the programmer as a control and display platform.** The Analyzer can be operated "concurrently" with the Programmer desktop. That is, you can switch to an analyzer session from the Select Model screen on the Programmer desktop, and you can toggle back and forth between an analyzer session and the Select Model screen using icons on the task bar.	The Medtronic Model 5311B A-V Pacing System Analyzer (PSA) is a hand-held microprocessor based **device designed to test the electrical performance of the pulse generator and the pacing lead system at the time of pacemaker implantation and during invasive pacemaker troubleshooting or evaluation procedures. The** model 5311B A-V PSA combines the functions for a multimode external pulse generator, a digital measuring device, and a data processor to provide the following capabilities: • External single and dual chamber pacing in one of 10 selectable pacing modes to support he patient during pacemaker implantation and pacing system test procedures. The 5311B PSA provides unipolar or bipolar pacing for both single and dual chamber applications. • Measurement of cardiac stimulation thresholds for voltage and current or pulse width. • P-wave/R-wave analysis for evaluation of the cardiac signals detected by the pacing lead system. Information provided includes the filtered and unfiltered voltage amplitude and the slew rate of the detected depolarization signal and an intracardiac electrogram taken from the pacing lead. • A test for retrograde conduction during evaluation of a dual-chamber lead system. This test is a feature of the intracardiac electrogram function. • Automatic calculation of pulse energy and lead resistance from measured pulse parameters. • Implantable pulse generator (IPG) tests include determination of the pacing mode and measurement of the pacing mode and measurement of up to 11 pacing parameters.	All	Same

Device Parameter	CareLink SmartSync™ Device Manager (Model 24970A) and Applications (D00U002, D00U001, M01G02, M01A02, M01G01, and M01A01) KXXXXXX	Medtronic Pacing System Analyzer (Model 2290) P890003/S065	Medtronic A-V Pacing System Analyzer (Model 5311B) K910595 07MAY1991	Primary Predicate	Difference
General Description (Con't.)			Other capabilities of the Model 5311B A-C PSA include rapid stimulation to 800 ppm in VOOAOO, or Doo pacing mode, total output inhibition in any pacing mode, and an emergency VVI pacing feature that provides immediate ventricular demand pacing at preselected parameter values by a single keystroke command. The PSA is a constant voltage device. That is, the pulse voltage is held constant at the adjusted value, while the resultant current flow is a function of lead system impedance (output load). Constant voltage is the type of output circuit used in most implantable pulse generators. External features of the Model 5311B A-V PSA include a membrane keyboard from which all PSA functions are controlled, a multifunction liquid crystal display (LCD), and a 12-charactoer thermal printer (Figure 1). Two jacks on the end of the PSA provide for connection of cables that link the PSA to the lead system for pacing and lead system tests or to the implantable pulse generator for parameter measurements. IPG tests may be conducted without interruption of the PSA pacing function The PSA is powered by four, 9V, alkaline batteries located under an access cover on the back of the de vice.	All	Same

Device Parameter	CareLink SmartSync™ Device Manager (Model 24970A) and Applications (D00U002, D00U001, M01G02, M01A02, M01G01, and M01A01) KXXXXXX	Medtronic Pacing System Analyzer (Model 2290) P890003/S065	Medtronic A-V Pacing System Analyzer (Model 5311B) K910595 07MAY1991	Primary Predicate	Difference
Indication for Use	The base is intended to be used as part of the CareLink SmartSync device manager system. **Clinicians use the base to analyze the electrical performance of cardiac leads during device implant or invasive troubleshooting.** Clinicians use the base's ECG connections along with the app display to view, measure, and record live cardiac waveforms. The base is intended to be used by healthcare professionals only in operating environments under direct medical supervision.	The Analyzer is intended for use by a **clinician to analyze the pacing and sensing performance of the cardiac lead system during the implant of a cardiac arrhythmia management device, or during invasive troubleshooting of a cardiac lead system.**	The Medtronic Model 5311B A-V Pacing **System Analyzer in intended for use by a physician to measure stimulation thresholds and test the implantable pulse generator and pacing lead system during the surgical procedures of pacemaker implantation or during invasive pacemaker troubleshooting or diagnostic procedures.** The Model 5311B A-V PSA is designed to pace the patient externally during pacing system test and implantation procedures. The pacing and test functions of the Model 5311B A-V PSA are intended for both single- and dual-chamber pacemaker applications.	Medtronic Pacing System Analyzer Model 2290	Same
Product Code	DTA, DTC 21 CFR 870.3720 21 CFR 870.3630 New 21 CFR 870.3605	KRG and OSR	DTC 21 CFR 870.3630	This medical device has been reclassified to Class II 18APR2016 21CFR870	Same

Device Parameter	CareLink SmartSync™ Device Manager (Model 24970A) and Applications (D00U002, D00U001, M01G02, M01A02, M01G01, and M01A01) KXXXXXX	Medtronic Pacing System Analyzer (Model 2290) P890003/S065	Medtronic A-V Pacing System Analyzer (Model 5311B) K910595 07MAY1991	Primary Predicate	Difference
Features	Clinicians use this data to perform these tasks: • Analyze electrical performance of cardiac leads during implant. • Assess proper placement of cardiac leads during implant. • View, measure, and document live cardiac waveforms. The PSA app includes these features for the analysis of cardiac leads: • Dual and single chamber pacing modes. • **Automatic measurement of P-wave and R-wave amplitudes**. • **Lead impedance measurement.** • **Real-time display of atrial and ventricular EGM and ECG waveforms.** • **Rapid atrial stimulation to 850 min−1 (ppm).** • **Advanced pulse width versus amplitude pacing threshold tests.** • Measurement reports. The base includes these features: • Analyzer hardware and patient cable connections to support electrical assessment of cardiac leads during implant. • ECG cable connections to collect live cardiac waveform data that can be viewed, measured, and recorded using the app running on your mobile device. • Bluetooth® wireless technology to communicate with the app running on your mobile device. • A cradle to charge the Medtronic 24967 Patient Connector (The 24967 patient connector is not the subject of this submission). • Optional USB connectivity to charge the patient connector. (The 24967 patient connector is not the subject of this submission).	■ **Automatic measurement of P- and R-wave amplitudes** and slew rates ■ **Automatic lead impedance measurement** ■ **Real-time display of atrial and ventricular EGM** ■ **Rapid atrial stimulation to 800 min-1 (ppm)** ■ **Advanced analysis features, including antegrade and retrograde conduction tests, and a pulse width versus amplitude threshold analysis** ■ Measurement reports Safety features The Analyzer has the following safety features: ■ Backup battery in the event of a power loss ■ Electrical isolation from the programmer ■ Emergency VVI pacing	Below are the functions of the PSA operating mode. For pacing and lead system tests, the Model 5410 Surgical Cable is used to connect the PSA to an indwelling lead system. • Pacing Mode and Parameter Adjustment • **Emergency VVI Pacing** • **Stimulation Threshold Measurement** • Lead System Resistance • **Filtered P-Wave / R-Wave Amplitude** • **Pulse Energy** • Slew Rate and Unfiltered Signal Amplitude • Intracardiac Electrogram • **Retrograde Conduction Test Function** • Inhibit Function • **Rapid Stimulation**	Medtronic Pacing System Analyzer Model 2290	Same
Longevity	5 year warranty	10 years	1 year warranty	NA	NA

Device Parameter	CareLink SmartSync™ Device Manager (Model 24970A) and Applications (D00U002, D00U001, M01G02, M01A02, M01G01, and M01A01) KXXXXXX	Medtronic Pacing System Analyzer (Model 2290) P890003/S065	Medtronic A-V Pacing System Analyzer (Model 5311B) K910595 07MAY1991	Primary Predicate	Difference
Volume and Footprint	The Base shall have the nominal dimensions of approximately: Length: 8.203" +/- 5% Width: 9.450" +/- 5% Thickness: 1.810" +/- 5%. The Base will have a maximum footprint of: 548 cm^2.	The Analyzer will be installed into the Model 2090 Expansion Bay. When installed the Analyzer will not change the physical size of the Model 2090 Programmer.	H x W x D: 3.4" x 4.0" x 9.0"	All	Same
Mass	The Base Station shall have a maximum weight of 0.91 kilograms (2.0 lbs.).	16 ounces (1 lbs.).	1.5 kg (3.3 lbs.)	All	Same
MRI Compatibility	No	No	No	All	Same
Basic Rate	30-200 pm	20-210 ppm	30-180 ppm	Medtronic Pacing System Analyzer Model 2290	Within the range but Same
High Pacing Rate	200-850 ppm	200-800 ppm	100 – 180 ppm	Medtronic Pacing System Analyzer Model 2290	Similar
Stimulation Amplitude	0.25 – 8.0 V	0.1 – 10 V	0.1 – 10 V	Medtronic Pacing System Analyzer Model 2290	Similar
Pulse Width	0.03 – 1.50 ms	0.02 – 1.5 ms	0.05 – 2.0 ms	Medtronic Pacing System Analyzer Model 2290	Same

Device Parameter	CareLink SmartSync™ Device Manager (Model 24970A) and Applications (D00U002, D00U001, M01G02, M01A02, M01G01, and M01A01) KXXXXXX	Medtronic Pacing System Analyzer (Model 2290) P890003/S065	Medtronic A-V Pacing System Analyzer (Model 5311B) K910595 07MAY1991	Primary Predicate	Difference
Sensitivity	0.15 – 11.30 mV	0.25 – 20 mV	0.75 – 10mV	Medtronic Pacing System Analyzer Model 2290	Similar
Refractory or Blanking	Atrial: 150 – 500 ms Ventricular: 150 – 500 ms	Atrial: 200-500 ms Ventricular: 250 ms	Atrial: 235 or 400 ms depending on mode Ventricular: 233 or 325 ms depending on mode	Medtronic Pacing System Analyzer Model 2290	Similar
Slew Rate	No	Yes	Yes	NA	NA
Pacing Modes	**VOO; VVI; AOO; AAI; DOO; DDD; DDI; ODO;** OOO	**VOO, VVI,AOO, AAI, DOO, DDD, VDD, ODO**	**VVI,** VVT, **VOO, AAI,** AAT, AOO, **DDD**, DVI, **DOO,** VDD	All	Same (excluding VVV mode)
Accessories	Model 2292 Analyzer Surgical Cable Model 5103 Analyzer Adaptor Model 5104 Analyzer Adaptor Model 5114 Adaptor Model 5833S/SL Disposable Surgical Cables Model 5436 Analyzer Patient Cable Model 5410/5410S Surgical Cable Model 5436 Patient Cable Model 8190 Analyzer Software Model 5832 Surgical cable **and additionally**: Model 5473 Ground cable Model 5437 ECG Interface cable Model 5437 A Adaptor Model 2090 EC ECG cable Model 2090 ECL ECG cable Model 9790 LA ECG leads Model 9790 XLA ECG leads Two AA Batteries	Model 2292 Analyzer Surgical Cable Model 5103 Analyzer Adaptor Model 5104 Analyzer Adaptor Model 5114 Adaptor Model 5833 Disposable Surgical Cable Model 5436 Analyzer Patient Cable Model 5410/5410S Surgical Cable Model 5436 Patient Cable Model 8190 Analyzer Software Replacement Batteries (9V)	The Model 5311B A-V PSA is supplied with batteries, technical literature, and the following accessory cables: Model 5401B Test Cable Model 5410 Surgical Cable Model 5803A Indifferent Lead	Medtronic Pacing System Analyzer Model 2290	Same

Performance Data

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

Biocompatibility testing

The biocompatibility evaluation for the CareLink SmartSync Device Manager, Pacing System Analyzer Base, Model 24970A was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The device was justified by similarity to the Medtronic Model 24967 patient connector (K163460). The battery of testing for materials used in the Model 24970A included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

The Model 24970A is considered non-tissue or patient contacting.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the CareLink SmartSync Device Manager, Pacing System Analyzer Base, Model 24970A, associated applications and non-medical mobile platform (i.e. Tablet) with associated cables as necessary for test. The system complies with the IEC 60601-1, standards for safety and the IEC 60601-1-2 third and fourth edition versions of the standard for EMC.

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." The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Mechanical Testing

The following is a list of testing performed:

- Inspection of the required mechanical design features and function
- Workmanship inspection concerning all external surfaces that can cause injury such as sharp edges or pinch points
- Product labeling inspection
- Forces required to activate controls
- Chemical resistance testing for effects of repeat cleaning cycles
- Environmental and drop testing
- Reliability testing of buttons, electrical contacts, user connector insertions, and replaceable or moving mechanical components
- Performance and robustness testing of the Articulated Lid

Animal Study

There were no formalized animal studies performed for this 510(k) submission.

Clinical Studies

There were no formalized clinical studies performed for this 510(k) submission.

Conclusions

The non-clinical data, the hardware and software verification and validation support and demonstrate that the CareLink SmartSync Device Manager, Pacing System Analyzer Base, Model 24970A should perform as intended in the specified use conditions and is substantially equivalent to the predicate device.