JUL 14 1997

2. 510(k) SUMMARY

A. General Information

Submitter's Name	Lorna J. Harmuth Product Regulation Manager
Company Name and Address	Medtronic, Inc. 7000 Central Avenue N.E. Minneapolis, MN 55432
Submission Date	April 22, 1997

B. Device Name and Classification

Device Generic Name	Pacing System Analyzer
Device Trade Name	Medtronic Model 5318 Temporary Pacemaker / Implant Tool
Classification Name/Number	Pacemaker Generator Function Analyzer 21 CFR 870.3630, Class III Product Code: DTC

C. Predicate Devices

Model Number	Document Control Number	Approval Date
5311B Pacing System Analyzer	K884331	January 10, 1989
	K910595	May 7, 1991

D. Device Description

The Medtronic Model 5318 Temporary Pacemaker / Implant Tool is a hand-held, temporary, battery-powered, external, single chamber pacemaker designed for antibradycardia pacing therapy in asynchronous or synchronous (demand) pacing modes and to test the electrical performance of implanted lead systems. The Model 5318 Temporary Pacemaker / Implant Tool can be used with transvenous or myocardial lead systems in either a bipolar or unipolar lead configuration. In

addition, the Model 5318 Temporary Pacemaker/ Implant Tool can be used to determine stimulation and sensing thresholds for temporary pacing. The device is connected to commercially available temporary or permanent pacing leads with patient cables.

The device incorporates the following features:

- Output Rate, Amplitude and Sensitivity control and display on base level screen
- Lead impedance measurement and display capability
- Adjustable Pulse Width from .06 - 2.0 ms (0.06-0.6 ms in 0.06 ms increments; 0.6-2.0 in 0.1 ms increments)
- Ouput Range: 0.1 V - 10.0 V
- Base Rate: 30 to 200 ppm (30-50 ppm in 5 ppm increments; 50-100 ppm in 2 ppm increments; 100-200 ppm in 5 ppm increments)
- Sensitivity Range: 0.5 mV - 20 mV in synchronous pacing modes
- Pacing mode determined by manual adjustments to output amplitude and sensitivity parameter settings
- Battery polarity reversal capability
- 10 second continuous operation at nominal values during battery replacement
- Self-test capability
- Pin-protected cables (no exposed pins)
- Pace and Sense indicators
- On-Screen messages
- Screen backlighting for adjustment in low-light level situations
- Control lock function which prevents the dials from being changed inadvertently
- Low battery indicator
- EMERGENCY key
- Reversion circuitry
- Pause capability

The Model 5318 Temporary Pacemaker / Implant Tool allows pacing parameter adjustments and pacing mode selections to be made with four dials and seven membrane keys located on the front side of the device. The dials are for RATE, OUTPUT, SENSITIVITY, and PULSE WIDTH. The seven membrane keys are: LOCK/UNLOCK, MEASURE, PULSE WIDTH, PAUSE, OFF, ON and EMERGENCY.

Device parameter setting information is provided to the user with two liquid crystal display (LCD) screens on the front of the device. The upper screen displays the parameters for basic pacing (rate, output and sensitivity) and device status. The lower screen displays: warnings and instructions to the user; pulse

width setting; and impedance measurements. A light source aids visibility for the LCD display under low-light conditions. Bails on the case allow the device to be hung from an IV pole or strapped to the mounting position of choice.

E. Intended Use

The Medtronic Model 5318 Temporary Pacemaker / Implant Tool is intended to be used in conjunction with a cardiac pacing lead system for temporary single chamber pacing in a clinical environment. The Model 5318 can be used where short-term demand (synchronous) or asynchronous pacing is indicated for therapeutic, prophylactic or diagnostic purposes.

Specific indications for temporary cardiac pacing include, but are not limited to, the following:

- Sick sinus syndrome
- Sinus bradycardia
- Atrial and/or ventricular arrhythmias
- Complete heart block
- Cardiac arrest
- Bradycardia with congestive heart failure
- Support, management, and evaluation of a patient before implantable pacemaker implantation
- Support during implantable pacemaker replacement
- Cardiac complications during invasive or surgical procedures
- Support following cardiac surgery
- Acute myocardial infarction complicated by heart block

The Model 5318 is also intended to be used by or on the order of a physician to determine sensing and stimulation thresholds and measure lead impedance of implantable lead systems during implantable pacemaker implantation.

Contraindications

There are no known contraindications to the use of temporary pacing as a means to control the heart rate. The patient's age and medical condition, however, may dictate the type of temporary pacemaker and lead system used by the physician.

Atrial Pacing

Atrial pacing is ineffective in the presence of atrial fibrillation or atrial flutter.

Single chamber atrial pacing is contraindicated in the presence of AV conduction disorders.

Asynchronous Pacing

Asynchronous pacing is contraindicated in the presence of intrinsic cardiac rhythms.

F. Comparison of Required Technological Characteristics

The Model 5318 Temporary Pacemaker / Implant Tool is substantially equivalent in design, intended use, function and performance to the Model 5311B Pacing System Analyzer. The Medtronic Model 5311B A-V Pacing System Analyzer is a hand-held microprocessor based device designed to provide temporary external stimulation and to test the pacing lead system at the time of pacemaker implantation and during invasive pacemaker troubleshooting or evaluation. The devices are substantially equivalent in device design, function, materials and intended use. The comparison of required characteristics is provided below.

Characteristics	Medtronic 5318 Temporary Pacemaker/Implant Tool	Medtronic 5311B Pacing System Analyzer
a. Product Labeling	Combined Technical and Operating Manual	Separate Technical and Operator's Manuals - Substantially equivalent indications, contraindications, warnings, precautions, adverse effects. See Attachment 3 for Model 5311B labeling.
b. Intended Use	Intended to be used in conjunction with a cardiac pacing lead system for temporary single chamber pacing in a clinical environment. The 5318 can be used where short-term synchronous or asynchronous pacing is indicated for therapeutic, prophylactic, or diagnostic purposes. The Model 5318 is also used to determine sensing and stimulation thresholds and measure lead impedance of implantable lead systems during implantable pacemaker implantation.	Intended for use by a physician to measure stimulation thresholds and test the IPG and pacing lead system during permanent pacemaker implantation or during invasive pacemaker troubleshooting or diagnostic procedures. The 5311B is designed to pace the patient externally during pacing pacing system test and implantation procedures. The pacing and test functions are intended for both single- and dual-chamber pacemaker applications.
c. Physical Characteristics	Hand held, battery operated, microprocessor based device.	SAME
d. Anatomical Sites	Single chamber of the heart, either atrial or ventricular.	Single or dual chambers of the heart, either atrial or ventricular.
e. Target Population	The 5318 can be used during permanent pacemaker implantation for testing or pacing in patients who require short-term, single chamber, synchronous or asynchronous pacing.	The 5311B can be used during permanent pacemaker implantation for testing or pacing in patients who require short-term, single or dual chamber, synchronous or asynchronous pacing.
f. Performance Testing	Fully tested for user interface, electrical,environmental and product integrity requirements.	SAME
g. Safety Characteristics	Two step operation required to turn off device. Low battery indicator. Emergency Pacing available. Reversible battery polarity. Continuous pacing operation during battery replacement. Keyboard lock feature. Pin-protected cable connections. Self-test function and runaway rate protection. Protection from defibrillation shock and electrostatic discharge. Minimized susceptibility to electromagnetic and magnetic interference.	Low battery indicator.

G. Summary of Studies

Medtronic has thoroughly evaluated the Model 5318 Temporary Pacemaker / Implant Tool and/or test assemblies through in-vitro testing to assure suitability and reliability for its intended use. All testing conducted on the Model 5318 Temporary Pacemaker / Implant Tool demonstrated that all design and manufacturing process requirements were met, and that the new device raises no new questions of safety or efficacy.

The following section provides a summary of the non-clinical testing performed on the Model 5318 Temporary Pacemaker / Implant Tool to ensure safety, reliability and performance according to Medtronic specifications. Electrical, mechanical, environmental and software testing and verification was all performed on the Model 5318 Temporary Pacemaker / Implant Tool.

User Interface Requirements

The Model 5318 Temporary Pacemaker / Implant Tool devices were tested to verify that the device meets the user interface requirements including proper mechanical operation of the device, control dials and keys, function of the indicators and physical requirements of the device. The following user interfaces were examined to ensure conformance to specifications:

- Dials
- Liquid-Crystal-Display (LCD)
- Membrane Keys
- Pace LED Indicator
- Sense LED Indicator
- Backlight
- Battery Compartment
- Attachment Mechanisms
- Weight
- Size

All of these tests showed that the device operated to Medtronic specification as shown by proper operation of all above characteristics under labeled usage conditions.

Electrical Conformance

The Model 5318 Temporary Pacemaker / Implant Tool devices were tested to verify that the device meets the electrical requirements. This testing consisted of examination of the function of the device under conditions similar to those found in normal usage. The following electrical requirements were examined to ensure conformance to specifications:

- Base Rate
- Rate Runaway Protection
- Waveform Integrity
- Sensitivity
- Pulse Width
- Impedance Measurement
- Output
- Frequency Response
- Refractory
- Blanking
- Pacing Modes
- Pacing Mode Transition Rules
- Emergency Mode
- Direct Current (DC) Rejection
- Alternating Current (AC) Rejection
- Common Mode Rejection
- Reversion
- Battery Life
- Performance Under Low Battery Conditions
- Operation After Battery Removal
- Power-On Self Test
- Serial Link

All of these tests showed that the device operated to Medtronic specification as shown by proper operation of all above characteristics under labeled usage conditions.

Environmental Requirements

The Model 5318 Temporary Pacemaker / Implant Tool devices were tested to verify that the device meets the environmental requirements. The following environmental requirements were examined to ensure conformance to specifications:

- Electromagnetic Compatibility (EMC)
- Defibrillation
- Electrocautery
- Electrostatic Discharge (ESD)
- Vibration
- Thermal Shock
- Mechanical Shock
- Spill Resistance
- Operating Temperature
- Storage Temperature

- Humidity Testing
- Safety Testing
- Chemical Resistance
- Sterilization
- Packaging and Handling

All of these tests showed that the device operated to Medtronic specification as shown by proper operation of all above characteristics under labeled usage conditions.

Predicted Reliability

A reliability assessment was performed according to MIL Standard 217 (Reliability Predictions of Electrical Equipment).

Software Development and Testing

Software Development and testing was conducted in accordance with formal procedures for the development and testing of software. These procedures include development of a Software Requirements Specification, a Software Design Description, a System Hazard Analysis, and a Verification Test Specification and Verification Test Plan. The software was tested per the Verification Test Specification and Verification Test Plan. Errors, anomalies, or inconsistencies were noted in Engineering Report Forms (ERFs), and all corrections were made and verified. A final configuration audit was performed by Quality Assurance to ensure that all documents and code were properly coded and released.

H. Conclusion

The bench testing presented herein provides reasonable assurance that the Medtronic Model 5318 Temporary Pacemaker / Implant Tool will perform as intended when used in accordance with its labeling. Additionally, based on similarities in design, materials, intended use and in-vitro test data, the 5318 Temporary Pacemaker / Implant Tool is considered substantially equivalent to the 5311B AV Pacing System Analyzer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lorna J. Harmuth
Product Regulation Manager
Medtronic, Inc.
7000 Central Avenue, N.E.
Minneapolis, Minnesota 55432-3576

JUL 14 1997

Re: K971474
Trade Name: Model 5318 Temporary Pacemaker/Implant Tool
Regulatory Class: III
Product Code: 74DTE
Dated: April 22, 1997
Received: April 23, 1997

Dear Ms. Harmuth:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Model 5318 Temporary Pacemaker / Implant Tool

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

per Joseph B. Tellin

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K971474

(Optional Format 1-2-96)