

JAN 21 2000

K994331

# 510(K) SUMMARY

## Submitter

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Medtronic, Inc.  
7000 Central Avenue N.E.  
Minneapolis, MN 55432

Contact: Nora K. Hadding, Sr. Product Regulation Manager  
Telephone: (612) 514-9945  
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Date Prepared: December 21, 1999

## Name of Device

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Trade Name: "Reveal® Plus Insertable Loop Recorder" (ILR) System. The system is composed of the Model 9526 implanted recorder and the Model 6191 Activator. The Model 9809E Reveal software, Model 9790 programmer and Model 9766A telemetry head are also part of the system

Common Name: insertable loop recorder

Classification Name: cardiac implantable event recorder (Product Code 74 MXC) (21 CFR 870.2800)

## Predicate Device

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The predicate device for the Reveal Plus ILR system is the Reveal ILR system.

## Device Description

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### System Description

The Reveal Plus ILR system is designed to record and store electrocardiogram (ECG) during symptomatic events. The system consists of the Model 9526 implanted recorder and the Model 6191 Activator. A Medtronic Model 9790 programmer equipped with a Medtronic Model 9766A radio frequency telemetry head and Model 9809E software is required for programming and retrieving data from the recorder.

The primary new feature of the Reveal Plus ILR is the auto-activation function, which supplements the patient-activated function. Patient activation remains the primary means to capture an event. Patient activation is important to document the patient's ECG when either an arrhythmic or non-arrhythmic event occurs, providing the clinician with a symptom-rhythm correlation. Storage of a patient-activated event with normal sinus rhythm helps the physician to rule out arrhythmic causes. Auto activation may be useful for patients who may be incapable of using the patient Activator or who are otherwise non-compliant.

## Packaging

Two package configurations are available. The Reveal Plus ILR system package contains the implanted recorder, the Activator, the Activator carrying case, the product information manual, and a patient information manual. A replacement Activator is available in the other package configuration. Both package configurations were fully validated.

## Intended Use

The Medtronic Model 9526 Reveal Insertable Loop Recorder is an implantable monitoring and recording system designed for diagnostic evaluation of patients who experience transient symptoms that may suggest a cardiac arrhythmia.

## Technological Characteristics

The following table outlines the functional similarities between the Reveal Plus ILR system and the Reveal ILR.

Device Feature	Reveal	Reveal Plus
Subcutaneous ECG Recording	Yes	Yes
Pre and Post Event Storage	Yes	Yes
Patient Activation	Yes	Yes
Auto Activation	No	Yes
Total Storage Time	21 or 42 min.*	Same
Maximum Single Event Storage Time	42 min.	42 min. Patient-Activated 2 min. Auto-Activated
Storage Modes	4 modes	8 modes
Number of Events	1 or 3	1 or 3 in Patient-Activated mode 6 or 14 in Auto-Activated mode
Data Retrieval	Radio-frequency telemetry	Same
Bandwidth	0.85-32 Hz	Same
Sampling Rate	100 Hz	Same
Volume	8 cc	Same
Mass	17 g	Same
Dimensions	61 x 19 x 8 mm	Same

\* 42 min. modes use data compression to increase storage time. Data sampled at 100 Hz is stored to memory at 50 Hz.

## **Summary of Studies**

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The following studies were performed to ensure that the Reveal Plus ILR system meets all of its design and performance requirements.

### **In Vitro/Bench Testing**

Mechanical, battery and package testing were not repeated because Reveal Plus uses a mechanical platform that is identical to the Reveal ILR system. To evaluate other aspects of the Reveal Plus ILR system, the following in vitro testing was completed:

Model 9526 implanted recorder testing (hybrid qualification testing and electromagnetic compatibility testing)

Model 6191 Activator testing.

The Reveal Plus ILR system passed all of the in vitro requirements.

### **In Vivo Testing**

A canine study was performed to evaluate the auto-activation feature prior to human use. The false activations were evaluated before and after adjustments to the sensitivity setting.

### **Biocompatibility Information**

Biocompatibility testing was not required because blood-contacting materials of the Reveal Plus ILR implanted device are the same as the predicate Reveal ILR.

### **Sterilization Validation**

The Model 9526 implanted recorder is sterilized using a 100% Ethylene Oxide (EtO) sterilization process. The sterilization process is identical to that used for the Reveal model 9525 implanted recorder because all materials and packaging are identical to the Reveal ILR.

### **Conclusion**

The testing described above provides reasonable assurance that the Reveal Plus ILR system will perform as intended when used in accordance with its labeling. Additionally, based on similarities in design, materials, in vitro test data and canine in vivo electrical performance, Medtronic considers the Reveal Plus ILR system to be substantially equivalent to the Reveal ILR system.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 21 2000

Ms. Nora K. Hadding  
Medtronic, Inc.  
4000 Lexington Avenue North  
Shoreview, MN 55126-2983

Re: K994331  
Reveal® Plus Insertable Loop Recorder System - Model 9526  
Implanted Recorder and Model 6191 Patient Activator  
Regulatory Class: II (two)  
Product Code: 74 MXC  
Dated: December 21, 1999  
Received: December 23, 1999

Dear Ms. Hadding:

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 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). 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 requirements, 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.

Page 2 - Ms. Nora K. Hadding

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/dsma/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.  
Acting Director  
Division of Cardiovascular,  
Respiratory, and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K994331

# INDICATIONS FOR USE

510(k) Number (if known): N/A K994331

Device Name: Reveal® Plus Insertable Loop Recorder

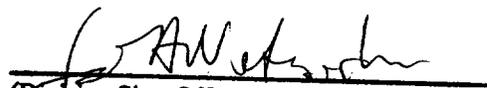
Indications For Use: The Medtronic Reveal Plus Insertable Loop Recorder is an implantable patient-activated monitoring system that records subcutaneous ECG and is indicated for patients who experience transient symptoms that may suggest a cardiac arrhythmia.

(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)

(Optional Format 1-2-96)



(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number \_\_\_\_\_