Medtronic Model 7250 Jewel®AF Implantable Cardioverter Defibrillator System - P980050/S1

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name:	Medtronic Model 7250 Jewel ® AF **Implantable Cardioverter Defibrillator** (ICD) System ["Atrial Fibrillation only" indication]; including: Model 9465 InCheck™ **Patient Assistant,** Model 6937A **Coronary Sinus (CS) Lead**, and **Superior Vena Cava (SVC)Lead**.
Manufacturer:	Medtronic, Inc.
Approval Date:	April 6, 2001
Approval Letter:	http://www.fda.gov/cdrh/pdf/p980050s001a.pdf

What is it and how does it work? The Model 7250 Jewel ® AF Implantable Cardioverter Defibrillator System (ICD System) is an implantable device that monitors heart rhythm, detecting and classifying those that are abnormal. It then stops an abnormal rhythm (arrhythmia) by delivering an electrical shock to the heart's upper (atrial) and/or lower (ventricular) chambers. The shock restores the heart's normal rhythm.

The *InCheck* **Patient Assistant** is a handheld, battery-powered device used by the patient to administer the electrical shock if he or she is experiencing symptoms and the system has not delivered a shock. When the patient presses the button on this device, the system determines whether an abnormal rhythm is occurring and whether an electrical shock is needed. If it is, the shock is delivered.

The Model 6937A Lead (CS lead) is an insulated wire placed in specific blood vessels to carry the implant's electrical current.

When is it used? The ICD System is used in patients who do not obtain symptomatic relief through medication and continue to have atrial fibrillation and/or life-threatening rapid ventricular contractions.

What will it accomplish? In the clinical study that supported this device, the device successfully restored the patient to a normal rhythm 91% of the time. Patients experienced improvements in their

physical functioning and decreases in the frequency and severity of their symptoms. The types of complications that patients experienced were typical of other pacemaker products, and included early abnormal rhythms, blood clots, and dislodgment of the lead.

When should it not be used? The ICD System should not be used in patients whose abnormally rapid heart rhythm may have temporary or reversible causes, e.g., acute heart attack (myocardial infarction) or heart medication overload. It also should not be used in patients who have continuous abnormalities in their heart rhythm.

Additional information: Summary of Safety and Effectiveness and labeling are available at: http://www.fda.gov/cdrh/pdf/p980050s001.html

Other: http://www.americanheart.org

(Updated 10/3/2001)