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

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** including the Model 6943 Atrial/Ventricular Lead
Manufacturer:	Medtronic**,** Inc.
Approval Date:	June 14, 2000
Approval Letter:	http://www.fda.gov/cdrh/pdf/p980050a.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 Model 6943 Atrial/Ventricular 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, it successfully restored the patient to a normal rhythm in 76 percent of the atrial episodes and in 88.6 percent of the ventricular episodes. Patients experienced improvements in their physical functioning and decreases in the frequency, duration, and severity of their symptoms. The types of complications that patients experienced were typical of other pacemaker products, and included reprogramming of the pacemaker, infection at the site of the implant, and dislodgment of the lead.

When should it not be used? **T**he 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/p980050.html

Other:
American Heart Association: http://www.americanheart.org

(Updated 10/11/2001)