Guidant Cardiac Resynchronization Therapy Defibrillator System including the CONTAK CD® pulse generator and the EASYTRAK® left ventricular coronary venous lead P010012

CONTAK CD
Pulse Generator and EASYTRAK Lead

(right atrial and right ventricular leads are not shown)

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:	CONTAK CD pulse generator and the EASYTRAK left ventricular coronary venous lead
Manufacturer:	Guidant Corporation
Address:	4100 Hamline Avenue North, St. Paul, MN 55112
Approval Date:	May 2, 2002
Approval Letter:	http://www.fda.gov/cdrh/pdf/P010012a.pdf

What is it and how does it work? The CONTAK CD® system is an implantable cardioverter defibrillator (ICD) that also delivers cardiac resynchronization therapy (CRT) for certain patients with advanced heart failure. The system consists of an implantable pulse generator, made up of a battery and electronic circuitry, connected to three leads (insulated wires). The pulse generator is usually implanted below the collarbone, just beneath the skin. One lead is placed in an upper heart chamber (the right atrium), a second lead is placed in a lower heart chamber (the right ventricle), and a third lead is placed in a vein that overlies the left ventricle. When the device is functioning as an ICD, it senses dangerous abnormal heart rhythms and shocks the heart back into a normal rhythm. The CRT portion of the device coordinates the beating of the left and right ventricles so that they work together more effectively to pump blood throughout the body.

When is it used? In certain patients who are at risk for life-threatening heart rhythm problems and also have symptoms of advanced heart failure despite taking heart failure medication. Symptoms of heart failure such as fatigue, shortness of breath and difficulty performing daily activities, are caused by the heart not pumping enough blood to meet the body's needs. In some of these patients, the lower heart chambers do not contract together and CRT helps coordinate the beating of the heart.

What will it accomplish? This device system will deliver a life-saving shock to return the heart to normal heart rhythm and prevent sudden cardiac death. It may also relieve some of the symptoms associated with heart failure, including shortness of breath and fatigue during exercise, and this may result in a better quality of life.

When should it not be used? It should not be used in patients whose heart failure or life-threatening heart rhythm abnormality are reversible or temporary. It should not be used on those patients who are not on the appropriate drugs for heart failure.

Additional information: Summary of Safety and Effectiveness is available at:
http://www.fda.gov/cdrh/pdf/P010012.html

Other:

- American Heart Association: http://www.americanheart.org/
- Information on Cardioverters: http://216.185.112.5/presenter.jhtml?identifier=11227
- Information on Healthy Lifestyle: http://216.185.112.5/presenter.jhtml?identifier=1200009
- Information on How the Heart Works: http://216.185.112.5/presenter.jhtml?identifier=1557
- National Institutes of Health: Information on arrhythmia: http://www.nhlbi.nih.gov/health/public/heart/other/arrhyth.htm
- Information on tachycardia: http://www.nlm.nih.gov/medlineplus/ency/article/000187.htm
- Drawing of tachycardia heart beats: http://www.nlm.nih.gov/medlineplus/ency/imagepage/18034.htm

(Updated 05/03/2002)