Microny SR+ Cardiac Pacemaker (Model 245T) - P970013

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:	Microny SR+ Cardiac Pacemaker (Model 245T)
Manufacturer:	St. Jude Medical
Address:	15900 Valley View Court, Sylmar, CA 91342
Approval Date:	December 21, 2000
Approval Letter:	http://www.fda.gov/cdrh/pdf/p970013a.pdf

What is it and how does it work? The Microny SR+ pacemaker is a small device that can be implanted in patients with irregular heart beats. It delivers electrical pulses to the heart when they are needed to produce a more normal heart rhythm. A sensor in the device adjusts the pacing rate according to the patient's activity level, increasing the pacing rate when the body needs increased blood circulation. It provides stimulation to only the heart chamber that requires stimulation and includes a programming device that allows the doctor to change the pacing mode from outside the patient's body.

When is it used and what will it accomplish? It is used in patients who have low or irregular heart rates. These patients often have symptoms such as fatigue, disorientation, fainting, loss of consciousness, or dizziness due to an abnormal heart rhythm.

When should it not be used? This device should not be used in patients with certain heart abnormalities. Also, programmed pacing at higher rates may be inappropriate for patients who experience chest pain (angina) or other heart-related pain.

Additional information: Summary of Safety and Effectiveness and labeling are available at: http://www.fda.gov/cdrh/pdf/p970013.html

Other

- FDA: http://www.fda.gov/fdac/features/1997/397_hart.html
- NIH: http://www.nhlbi.nih.gov/health/public/heart/other/arrhyth.htm

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

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