New Device Approvals

INTEGRITY™ AFx DR
MODEL 5346
P880086/S083 (Generator) &
P830045/S076 (Programmer)

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:	Integrity™ AFx DR Model 5346 (Cardiac Pacemaker)
Manufacturer:	St. Jude Medical
Address:	15900 Valley View Court, Sylmar, CA 91342
Approval Date:	July 11, 2001
Approval Letter:	http://www.fda.gov/cdrh/pdf/p880086s083a.pdf

What is it? This device is an implanted pacemaker that provides timed electrical stimuli to the heart. It consists of the pulse generator (battery and electronic circuitry) and the leads (insulated wires) which carry electronic impulses between the generator and the heart. It has features for automatically delivering pulses to establish a normal heart rhythm, as well as suppressing abnormally rapid electrical signals in the upper (atrial) heart chambers, called atrial tachyarrhythmias. These include atrial fibrillation, which is a very disorganized, rapid electrical disturbance in the upper chambers of the heart.

How does it work? The device is externally programmable, meaning that the settings can be adjusted from outside the body. It provides dual chamber pacing, so that it can deliver stimuli to both the upper (atrial) and lower (ventricular) heart chambers. It is equipped with automatic rate-adjusting control circuits, patient safety features, and extensive diagnostic tools and tests.

When is it used? It is used in patients whose hearts cannot maintain a normal rhythm. Symptoms of this may include dizziness, fainting, fatigue, disorientation, or loss of consciousness. It is also used in patients with abnormally rapid beating of the heart's upper chambers (see above).

What will it accomplish? It will benefit patients who have pacemaker indications and/or atrial tachyarrhythmias, including intermittent or persistent atrial fibrillation.

When should it not be used? There are several medical conditions and situations in which this device should not be used. For example, it should not be used in patients who have or are indicated for an ICD (implanted cardioverter defibrillator). It also may not be appropriate for patients with heart-related chest pain (angina) or abnormalities of the heart muscle.

Additional information: Summary of Safety and Effectiveness is available at:
http://www.fda.gov/cdrh/pdf/p880086s083.html

Other:

- American Heart Association: http://www.americanheart.org **
- NIH**: http://medlineplus.nlm.nih.gov/medlineplus/ency/article/000184.htm
- http://www.bu.edu/cohis/cardvasc/cvd.htm **

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(Updated 08-29-2001)