Cordis Checkmate™ System

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: Cordis Checkmate™ System
Manufacturer: Cordis Corporation
Address: PO Box 025700, Miama, Florida 33102-5700
Approval Date: November 3, 2000
Approval Letter: http://www.fda.gov/cdrh/pdf/p990036a.pdf

What is it? The Cordis Checkmate System consists of the following components: a closed end delivery catheter (hollow tube), a non-radioactive ribbon, radioactive ribbons with different numbers of radioactive seeds and a storage container for the radioactive ribbons. The radioactive seeds use a type of radiation called gamma radiation.

How does it work? Using an X-ray machine in a cardiac catheterization laboratory, the physician places the delivery catheter in the coronary artery at the site of the in-stent restenosis (blockage in the artery). The non-radioactive ribbon is used to verify that the delivery catheter is in the right location to deliver the radiation treatment. After ensuring that the delivery catheter is in the right location, the radioactive ribbon is removed from the storage container and placed in the delivery catheter for an appropriate length of time to deliver radiation to the artery. At the completion of the radiation treatment, the radioactive ribbon is returned to the storage container.

When is it used? The Cordis Checkmate System is used in patients who have "in-stent" restenosis. In-stent restenosis is a re-blockage inside a coronary artery at the site of previous stent placement. A stent is an expandable metal tube that is placed inside an artery to help keep an artery open at a site of narrowing.

What will it accomplish? In-stent restenosis (re-blockage) may occur after placement of a stent in a coronary artery. This type of restenosis may be caused by an increased amount of scar tissue in the artery at the site of stent placement. The radiation treatment delivered by the source ribbon is intended to interrupt scar tissue growth and thus reduce the occurrence of "in-stent" restenosis or re-blockage of the coronary artery at the site of previous stent placement.

When should it not be used? The Cordis Checkmate System should not be used in patients who are not good candidates for blood thinning drugs or antiplatelet therapy.

Additional information: Summary of Safety and Effectiveness is available at:
http://www.fda.gov/cdrh/pdf/p990036.html
Other: http://www.americanheart.org , http://jama.ama-assn.org/issues/v285n1/ffull/jfd00011-1.html