Bio*divYsio*™ AS PC (phosphorylcholine) Coated Stent Delivery System- P000011

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:	Bio*divYsio*™ AS PC (phosphorylcholine) Coated Stent Delivery System
Manufacturer:	Biocompatibles Cardiovascular Inc.
Address:	Ten Almaden Boulevard, Suite 1600, San Jose, CA 95113
Approval Date:	September 29, 2000
Approval Letter:	http://www.fda.gov/cdrh/pdf/p000011a.pdf

What is it? The Bio*divYsio*™ AS is a small stainless steel wire mesh stent which is permanently implanted within the opening of a blocked coronary artery (artery in the heart) to expand its inner diameter by acting as a "scaffolding". This allows improved blood flow through the artery.

How does it work? The Bio*divYsio*™ AS stent is inserted into the femoral artery in the groin area and threaded up to the heart, where it is placed in the narrowed coronary artery. The artery is first opened by expanding a balloon within it, in a procedure called angioplasty. Then the stent is placed in position within the artery. This keeps it open so that blood can flow to the heart muscle.

When is it used? Like other stents, the Bio*divYsio*™ AS is used in patients with narrowed coronary arteries, preventing sufficient blood flow to the heart (ischemic heart disease). This condition often produces symptoms such as light-headedness, dizziness, or fainting.

What will it accomplish? The Bio*divYsio*™ AS stent opens the narrowed coronary artery and keeps it open for blood to flow to the heart muscle. Results from a randomized clinical trial at 35 North American centers, with a total of 686 patients, demonstrated that the 6-month failure rate was equivalent to an existing stent (7.99% vs. 7.12%, respectively). An x-ray study of the stented coronary arteries at 6 months demonstrated that recurrence of artery blockage (restenosis) for the Bio*divYsio* stent was equivalent (19.90% vs. 20.13%) to the control stent.

When should it not be used? The BiodivYsio™ AS should not be used in patients who can not tolerate or have contraindications for blood-thinning drugs, as in antiplatelet or anticoagulant therapy.

Additional information: Summary of Safety and Effectiveness is available at: http://www.fda.gov/cdrh/pdf/p000011.html

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

(*Updated 3/8/01)*