



New Device Approvals

Mosaic Porcine Bioprosthesis, Model 305 (Aortic) and Model 310 (Mitral) - P990064

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: Mosaic Porcine Bioprosthesis, Model 305 (Aortic) and Model 310 (Mitral)
Manufacturer: Medtronic, Inc.
Address: Medtronic Heart Valves, 1851 East Deere Avenue, Santa Ana, CA 92705
Approval Date: July 14, 2000
Approval Letter: <http://www.fda.gov/cdrh/pdf/p990064a.pdf>

What is it? The Mosaic Porcine Bioprosthesis is an implantable heart valve made from the heart valve of a pig. It is used to replace one or more of the heart's natural valves when they are damaged. In addition to the valve itself, the device includes a plastic support structure called a stent. When implanted, the device is used either to control blood flow through the heart or blood flow from the heart into the aorta (the main artery leading from the heart).

How does it work? Like the heart's natural valves, it allows blood to flow in one direction only. When used as the valve between the left upper and left lower heart chamber, it replaces the mitral valve; when used as a valve between the left lower heart chamber and the great artery (the aorta), it replaces the aortic valve.

When is it used? When either the heart's natural valves, or a previously implanted artificial valve, is not working properly and needs to be replaced.

What will it accomplish? The Mosaic Porcine Bioprosthesis ensures that blood flows in the proper one-way direction through the heart.

When should it not be used? For a patient who needs a heart valve, there are no specific situations where this valve cannot be used. In each case, the physician must decide whether this type of valve is best, or whether another type should be used.

Additional information: Summary of Safety and Effectiveness and labeling are available at: <http://www.fda.gov/cdrh/pdf/p990064.html>

Other:

NIH: <http://www.nlm.nih.gov/medlineplus/heartvalvediseases.html>

<http://www.nia.nih.gov/health/pubs/hearts-arteries/p4.htm#p41>

American Heart Association: http://www.americanheart.org/Heart_and_Stroke_A_Z_Guide/heartv.html

(Updated 10/11/2001)