NNMT Medical, Inc. CardioSEAL® Septal Occlusion System with QwikLoad™ - P000049

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:	NMT Medical, Inc. CardioSEAL® Septal Occlusion System with QwikLoad™
Manufacturer:	NMT Medical, Inc.
Address:	27 Wormwood Street, Boston MA 02210
Approval Date:	December 5, 2001
Approval Letter:	http://www.fda.gov/cdrh/pdf/P000049a.pdf

What is it? The CardioSEAL® Septal Occlusion System with QwikLoad™ is a device used to close an abnormal opening in the wall between the lower chambers of the heart (the ventricles). The opening is called a ventricular septal defect.

There are two parts to the device: (1) a delivery catheter and (2) a permanent implant. The delivery catheter is used to transport the implant to the site of the defect in the heart. The implant is the part that remains permanently in the heart to block the hole.

Drawing of a ventricular septal defect

How does it work? The procedure takes place in a cardiac catheterization laboratory. The implant is placed by advancing the delivery catheter through blood vessels to the site of the defect inside the heart. A physician uses an x-ray machine during placement of the implant to help view the procedure. Once the physician is certain the implant is properly placed to cover the defect, the implant is released from the delivery catheter. The implant remains in the heart and the delivery catheter is removed.

When is it used? This device is used in certain high-risk patients with complex ventricular septal defects that are large enough to require closure, but, based on their location, may be difficult to close using surgery.

What will it accomplish? The implant is designed to permanently close the defect in the heart.

When should it not be used? The CardioSEAL® Septal Occlusion System with QwikLoad™ should not be used in patients with:

- Defects that occur after a heart attack;
- Coagulation or clotting disorders who are unable to take blood thinning drugs;
- Blood clots near the site where the implant is to be placed;
- Blood clots in the blood vessels through which the delivery catheter will be advanced;
- Blood vessels that are too small to allow the advancement of the delivery catheter or the proper positioning of the implant;
- Certain active infections.

Additional information: Summary of Safety and Effectiveness and labeling are available at: http://www.fda.gov/cdrh/pdf/p000049.html

Other:

- Information on ventricular septal defect
- Information on heart defect corrective surgery
- Latest news, diagnosis, symptoms, management nutrition, treatment, dictionaries, organizations

(Updated 08/01/2002)