



New Device Approvals

Activa® Parkinson's Control System P960009/S7



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: Activa® Parkinson's Control System
Manufacturer: Medtronic, Inc.
Address: 800 53rd Avenue NE, Minneapolis, MN 55421
Approval Date: January 14, 2002
Approval Letter: <http://www.fda.gov/cdrh/pdf/p960009S7a.pdf>

What is it? A totally implanted brain stimulator to reduce the symptoms associated with advanced Parkinson's disease that are not adequately controlled with medications.

How does it work? A pulse generator (IPG) implanted under the skin of the abdomen or collar bone sends a constant stream of tiny electrical pulses through a series of leads (wires) to electrodes in selected areas of the brain. The electrical impulses block the tremors associated with Parkinson's disease.

Two separate device systems may be implanted to stimulate both sides of the brain to relieve symptoms on both sides of the body. To turn the stimulator on and off, the patient holds a magnet over the pulse generator. The device was initially approved in 1997 for use in one side of the brain to help control tremors on one side of the body

When is it used? This device is indicated for use with medications to aid in the management of the

symptoms of advanced Parkinson's disease.

What will it accomplish? The Activa® Parkinson's Control System may improve some of the symptoms associated with Parkinson's disease. However, individual results vary and the specific benefit for an individual patient cannot be predicted.

When should it not be used? It should not be used in patients who will be exposed to diathermy, or to MRI exams of the body, the head, or the chest. Also, it should not be used in patients who do poorly with the stimulation test, or who are unable to properly operate the brain stimulator.

Additional information: Summary of Safety and Effectiveness is available at:
<http://www.fda.gov/cdrh/pdf/p960009S7.html>

(Updated 05/01/2002)