Genesis Neurostimulation (IPG) System - P010032

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:	Genesis Neuromodulation (IPG) System
Manufacturer:	Advanced Neuromodulation Sysytems (ANS), Inc.
Address:	6501 Windcrest Dr., Suite 100, Plano, TX 75024
Approval Date:	November 21, 2001
Approval Letter:	http://www.fda.gov/cdrh/pdf/P010032a.pdf

What is it? This is a neurostimulation device system that includes a device implanted under the skin that sends electrical signals to the spinal cord to decrease severe chronic pain in the body, the arms, and the legs. The implanted device is an electrical signal generator and is connected to an insulated lead wire that contacts the spinal cord. The electrical signal generator is controlled by an external device called a Patient Programmer that programs the treatment delivered by the signal generator.

How does it work? The implanted device receives radio signals from the external Patient Programmer. The radio signals tell the electrical generator when and what kind of stimulation to deliver to the spinal cord. The external Patient Programmer is battery operated and can be controlled by the patient or a health care provider.

When is it used? This device is used as an aid in the management of chronic difficult to treat pain of the trunk and limbs, including pain associated with failed back surgery syndrome, low back pain, and leg pain.

What will it accomplish? Decreased pain.

When should it not be used? Spinal cord stimulation is not recommended for patients who:

- are considered by their physicians to be poor surgical risk
- have multiple illnesses or active general infections
- are unable to operate the system

- fail to receive effective pain relief during trial stimulation

What are the precautions for patients with this device? Individuals who have the implanted neurostimulation system should avoid:

- diathermy treatments of any kind, including short-wave, microwave and therapeutic ultrasound
- MRI (magnetic resonance imaging).
- certain types of theft detectors and metal screening devices, such as those used at entrances of department stores, other public establishments, and airport security screening devices.

Additional information: Summary of Safety and Effectiveness and labeling are available at: http://www.fda.gov/cdrh/pdf/p010032.html

Other:
National Institutes of Health (NIH):

- Spinal Cord Diseases: http://medlineplus.nlm.nih.gov/medlineplus/spinalcorddiseases.html
- Spinal Cord Injuries: http://medlineplus.nlm.nih.gov/medlineplus/spinalcordinjuries.html
- Spinal Diseases: http://medlineplus.nlm.nih.gov/medlineplus/spinaldiseases.html

(Updated 04/29/2002)