



# New Device Approvals

## **SOUNDTEC® Direct Drive Hearing System P010023**



*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: SOUNDTEC® Direct Drive Hearing System (DDHS)  
Manufacturer: SOUNDTEC, Inc.  
Address: 2601 Northwest Highway, Suite 400, Oklahoma City, OK 73112  
Approval Date: September 7, 2001  
Approval Letter: <http://www.fda.gov/cdrh/pdf/p010023a.pdf>

**What is it?** The DDHS is a device to aid hearing. It has a piece worn externally in and behind the ear and a piece that is surgically implanted in the middle ear.

**How does it work?** The DDHS changes sound into an electronic signal and sends it to a magnet attached to the middle ear bones. The magnet causes the middle ear bones to vibrate, sending the sound on to the brain.

**When is it used and what will it accomplish?** The DDHS helps patients with hearing loss regain the ability to hear. It may be useful for adults who have moderate to severe sensorineural hearing loss. Sensorineural hearing loss, sometimes called "nerve deafness," is the reduced ability to hear because nerves for hearing do not work well. Patients may choose this device if they want an alternative to a conventional hearing aid.

**When should it not be used?** Patients who have any of the following conditions should not use the DDHS.

- Hearing loss that involves more than the hearing nerves
- Active middle ear infections
- Eardrum perforations from recurrent middle ear infections.

The strong magnetic fields in a magnetic resonance imaging (MRI) area may affect the device. Thus, patients with the implant may not have MRI exams or be in strong magnetic fields until the device has been surgically removed.

**Additional information:** The SSED and Labeling will be available at:  
<http://www.fda.gov/cdrh/pdf/p010023.html>

**Other:**

National Institute on Deafness and Communication Disorders: <http://www.nidcd.nih.gov/health/hb.htm>

*(Updated 4/19/2002)*