



# New Device Approvals

## Nucleus 24 Auditory Brainstem Implant System- P000015

*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: Nucleus 24 Auditory Brainstem Implant System  
Manufacturer: Cochlear Corporation  
Address: 61 Inverness Drive East, Suite 200, Englewood, CO 80112  
Approval Date: October 20, 2000  
Approval Letter: <http://www.fda.gov/cdrh/pdf/p000015a.pdf>

What is it? The Nucleus 24 Auditory Brainstem Implant (ABI) System is designed to restore some hearing in people who become deaf when surgery to remove auditory nerve tumors damages the nerves. The auditory nerves are the nerves responsible for hearing. The system includes both surgically implanted and externally worn components.

How does it work? The system consists of a receiver/stimulator, a pocket sized speech processor worn on the body, and the microphone/headset. During surgery, the receiver/stimulator is implanted behind the ear. A wire leads from the receiver/stimulator to a series of electrodes that are implanted into the brainstem. The speech processor and microphone/headset pick up sound and change it into electrical impulses that are sent to the implanted receiver/stimulator. The impulses travel down the wire to the electrodes, which electrically stimulate the area that normally receives the electrical signal from the ear.

When is it used? The device is used in teenagers and adults who have a rare disease (neurofibromatosis type 2) in which tumors growing on cranial nerves need to be surgically removed. Removal of tumors on the auditory cranial nerves requires severing or cutting the nerves, which results in total loss of hearing. These patients cannot be helped by hearing aids or cochlear implants.

What will it accomplish? In clinical studies, 82% of the patients implanted with the Nucleus 24 Auditory Brainstem Implant System were able to detect certain familiar sounds, such as honking horns and ringing doorbells; 85 % were able to hear and understand conversation with the aid of lipreading; 12% were able to hear well enough to use the phone. Of the 90 patients who received this implant 18% were not able to hear any sound. The ABI System does not restore normal hearing.

What are the risks? Patients are exposed to the normal risks associated with surgery and general anesthesia.

Additional information: The firm has developed a user manual, which includes information on how to use the device and what to expect during post-operative care. Summary of Safety and Effectiveness is available at:

<http://www.fda.gov/cdrh/pdf/p000015.html>

- FDA Talk Paper: <http://www.fda.gov/bbs/topics/ANSWERS/ANS01049.html>
- Panel Summary: <http://www.fda.gov/cdrh/entdp.html#072000>

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