

October 24, 2000

FDA Approves Hearing Device Implant

By **THE ASSOCIATED PRESS**

Filed at 1:50 a.m. ET

WASHINGTON (AP) -- The Food and Drug Administration has approved a brain implant device that may restore some hearing for patients who became deaf after tumors were removed from auditory nerves.

The device, called the Nucleus 24 Multichannel Auditory Brainstem Implant, or ABI, is approved for use in teen-agers and adults with neurofibromatosis Type II, an inherited condition that affects about one American in 40,000.

The ABI is the first hearing-assisting device approved for implanting in the brainstem. Another device, called the cochlear implant, is surgically implanted near the inner ear and is designed to help patients with a different type of hearing loss.

Patients with neurofibromatosis type 2, or NF2, develop tumors on the cranial and spinal nerves. Often the auditory nerves, which carry hearing signals to the brain, are affected. Removing the tumors often requires severing the auditory nerves. With the nerves cut, electrical signals from the ear cannot reach the brain, causing deafness.

The ABI device is implanted in the brain where it electrically stimulates an area that normally receives signals from the ear. A pocket-sized speech processor, worn by the patient, picks up sounds, changes them to electrical pulses and relays the pulses to the device implanted in the brain.

An FDA statement said the agency expedited review and approval of the device.

Approval was based on an evaluation of 60 patients in whom the device was implanted during treatment for NF2. After six months, 82 percent of the patients could detect familiar sounds, such as honking horns and ringing doorbells. About 85 percent could understand conversation with the aid of lip reading, and 12 percent could hear well enough to use the phone, the FDA said.

About 18 percent of the patients who received the device were unable to hear any sound, possibly because the device moved or because it was placed improperly, the statement said.

The ABI is made by the Cochlear Corp. of Englewood, Colo. A spokesman said the ABI now is available at about 10 clinics nationally at a cost of about \$30,000.

^-----

On the Net:

Cochlear Corp.: <http://www.cochlear.com>

House Ear Institute for information on ABI: <http://www.hei.org>