Vibrant Soundbridge

This is a brief overview of information related to FDA's approval to market this product. See 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: Vibrant Soundbridge
Manufacturer: Symphonix Devices, Inc.
Address: 2331 Zanker Road, San Jose, California 95131
Approval Date: August 31, 2000
Approval Letter: http://www.fda.gov/cdrh/pdf/p990052a.pdf

What is it? The Vibrant Soundbridge is a surgically implanted hearing device intended to help adults with moderate to severe nerve hearing loss.

How does it work? The device is implanted behind the ear in the temporal (skull) bone. It converts sound to mechanical energy that is transferred to the middle ear. This energy vibrates delicate structures in the middle ear very much the way normal sound does. The brain interprets the vibrations as sound. During the implant surgery, the surgeon implants a receiver behind the ear. A wire leads from the receiver to a small electromagnet attached to one of the middle ear bones.

When is it used? As an alternative to traditional hearing aids, adults with a moderate to severe sensorineural hearing loss may choose this device. Adults who choose this device should have already tried using appropriately fit hearing aids.

What will it accomplish? In clinical studies, the Vibrant Soundbridge was compared to the patient's own hearing aid. The patients had improved sound clarity and overall sound quality; better overall fit and comfort; reduced feedback; equal or increased functional gain; improved perceived benefit in many listening situations; and reduced ear wax and moisture. Study results showed that patients could understand speech about as well with the implant as with hearing aids.

When should it not be used? There are no restrictions on when the device should be used. However, patients with the Vibrant Soundbridge may not have Magnetic Resonance Imaging (MRI) of any type because the Vibrant Soundbridge has an implanted magnet that is a potential safety problem -- the magnetic field of the MRI could dislodge the implant

Additional information?: The Summary of Safety and Effectiveness and product labeling can be obtained at: http://www.fda.gov/cdrh/pdf/p990052.html
Other: http://jama.ama-assn.org/issues/v284n13/ffull/jfd00008-3.html