AUG - 9 1996

II. SUMMARY OF SAFETY AND EFFECTIVENESS

A. Name and Address

The Summary of Safety and Effectiveness is being submitted by Nobelpharma USA, Inc., 777 Oakmont Lane, Suite 100, Westmont, IL 60559. Our telephone number is: (708) 654-9100 and the contact person will be the Director, Regulatory Affairs. This summary was prepared on December 15, 1995.

B. Name of the Device

This device is generally known as a bone-anchored, bone conduction hearing aid with the trade name "BRÅNEMARK Bone-Anchored Hearing Aid (BAHA™) System."

C. The Predicate Product

The predicate product used in this Premarket Notification is the BRÅNEMARK SYSTEM® - Bone-Anchored Craniofacial Prosthetic Attachment System (K945154), the Audiant Bone Conduction Hearing Aid (K861971, K872168 and K841432), and other bone conduction hearing aids.

D. Description of the Device

The BRÅNEMARK Bone-Anchored Hearing Aid (BAHA™) System includes a titanium fixture which is placed in the temporal bone just behind the ear, an abutment, various accessories necessary for the placement and use of the fixture/abutment pillar, and a sound processor which is attached to the abutment. The fixture/abutment pillar is used as an anchor for the sound processor.

E. Intended Use of the Device

The BRÅNEMARK Bone-Anchored Hearing Aid (BAHA™) System is intended to be used as a bone-anchored, bone-conduction hearing aid. The device is indicated for use in patients requiring hearing amplification and with the following conditions:

1) <u>Otological</u>

- congenital malformations of the external ear or microtia
- chronically draining ear which does not allow use of an air conduction hearing aid (e.g. external otitis, draining mastoid cavity)

- other acquired malformations of the middle or external ear which preclude the wearing of a conventional hearing aid
- patients presently wearing, but dissatisfied with, traditional bone conduction hearing aids or patients who are satisfied with their bone conduction aids but could benefit from the features of the BAHA-type device.
- patients with conductive hearing loss due to ossicular disease and not appropriate for surgical correction or unable to be aided by conventional air conduction hearing devices.

2) Audiological

- Pure tone average bone conduction threshold of the indicated ear better than or equal to 45 dB HL for model, Classic 300 and 60 dB HL for model HC-220 (average 500, 1k, 2k and 3k Hz); and a speech discrimination score better than 60% or reasonably good speech discrimination as evaluated by a qualified audiologist, based on the patient's particular needs.

3) Psychosocial

- patients (either by themselves or with the aid of others) must be able to maintain the abutment/skin interface of the BAHA. Therefore, careful consideration must be given as to the patient's psychological, physical, emotional and developmental capabilities to maintain hygiene. Patients should be at least 3 years of age.

4) Anatomical and Biological

- Biologically, titanium implants can be installed in most patients. Sufficient bone volume and bone quality should be present for a successful fixture implantation. Alternative treatments should be considered for patients having a disease state that might jeopardize osseointegration.

F. Comparison of Technological Characteristics

The technological characteristics between the attachment system, the sound processor and the respective predicate products are substantially identical and no additional questions regarding safety and effectiveness exist.