3/31/99

K990601

510(k) Summary of Safety and Effectiveness

Trade Name:	Bojrab Micro-TORP Prosthesis
Common Name:	Total Ossicular Replacement Prosthesis
Classification Name:	Total Ossicular Replacement Prosthesis (§ 874.3495)
Official Contact:	Alicia E. Farage Senior Regulatory Affairs Specialist Smith & Nephew, Inc. ENT Division 2925 Appling Road Bartlett, TN 38133
Telephone:	(901) 373-0200
Telefax:	(901) 373-0242
Date Prepared:	February 22, 1999

The Bojrab Micro-TORP Prosthesis is substantially equivalent to the Black Oval-Top TORP marketed by Smith & Nephew, Inc., ENT Division, and the Schwaber Total implant marketed by Xomed. These devices have the same indications for use, total reconstruction of the ossicular chain that has lost its function due to disease, trauma, or congenital defect. The head of the Bojrab Micro-TORP Prosthesis is made from Hydroxylapatite, a widely accepted material for middle ear reconstruction, as are the heads of the two predicate devices. The Bojrab Micro-TORP Prosthesis and the predicate devices all have trimmable shafts. The Bojrab and Black implant shafts are made from HAPEX and the Schwaber implant shaft is manufactured from FLEX H/A.

Differences between the Bojrab Micro-TORP Prosthesis and the predicate devices should not affect the safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 31 1999

Ms. Alicia E. Farage
Sr. Regulatory Affairs Specialist
Smith & Nephew, Inc.
2925 Appling Road
Bartlett, TN 38133

Re: K990601
Trade Name: Bojrab Micro-TORP Prosthesis
Regulatory Class: II
Product Code: 87 ETA
Dated: March 4, 1999
Received: March 5, 1999

Dear Ms. Farage:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K990601
Device Name: Bojrab Micro-TORP®

Indications For Use:

- Otosclerosis
- Congenital fixation of the stapes
- When previous remedial surgery has been unsuccessful for the treatment of hearing loss due to otosclerosis, and a significant conductive loss remains with good cochlear reserve.
- Chronic middle ear disease
- Trauma

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K990601

Prescription Use ✓
(Per 21 CFR 801.109)

Karen Baker (for HPS)