NOV 23 1999

K992994

ENT Division

Smith & Nephew, Inc.
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Smith+Nephew

510(k) Summary of Safety and Effectiveness

Trade Name:	The Turbo 7000™ System
Common Name:	Electrical Surgical Drill/Shaver
Classification Name:	Surgical ENT drill, electric or pneumatic including handpieces and ENT burr/blades
Official Contact:	Jeff Cobb Group Director Regulatory, Clinical & Quality Assurance Smith & Nephew, INC. ENT Division 2925 Appling Road Bartlett, TN 38133
Telephone:	(901) 373-0200
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Date Prepared:	September 3, 1999

The Turbo 7000™ System is substantially equivalent to the Xomed XPS™ System used with the STRAIGHTSHOT™, PERFORMA™ and SKEETER™ handpieces, and the Modified ESSential Shaver.

The Turbo 7000 System's intended use is the cutting and removal of bone and tissue in general ENT, head & neck, and otoneurologic procedures. Otology procedures would include mastoidectomy and mastoidotomy. Sinus applications would embody septoplasty and procedures such as the removal of septal spurs, polypectomy, antrostomy, ethmoidectomy/sphenoethmoidectomy, frontal sinus trephination and irrigation, frontal sinus drill out, endoscopic DCR and trans-sphenoidal procedures. Nasopharyngeal/Laryngeal procedures would comprise adenoidectomy, tracheal, laryngeal polyectomy, laryngeal lesion debulking and tonsillectomy. Head and neck procedures would encompass soft tissue shaving, rhinoplasty (narrowing of the bony vault and revision of the bony pyramid), removal of fatty (adipose) tissue (lipo debridement) in the maxillary and mandibular regions of the face, and acoustic neuroma removal. Additionally, an irrigation pump will be included as a component of the system to provide irrigant in conjunction with the procedures.

The Turbo 7000 System that is described in this notification has the same technological characteristics, power modality and mode of operation as the predicate devices. The intended uses are substantially equivalent to the described predicate Modified ESSential Shaver System and the Xomed System. The Turbo 7000 System is designed to meet *UL 2601-1 including German Deviations and Australian Deviations, CSA 22.2 No. 601-1, IEC 601-1-1 (EN 60601-1), IEC 601-1-2(EN 60601-1-2) and IEC 529.*

Differences between the Turbo 7000 System 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

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Mr. Jeff Cobb
Group Director
Regulatory, Clinical & Quality Assurance
Smith & Nephew, Inc.
ENT Division
2925 Appling Road
Bartlett, TN 38133

Re: K992994
Trade Name: The Turbo 7000™ System
Regulatory Class: II
Product Code: 874.4250
Dated: September 3, 1999
Received: September 7, 1999

Dear Cobb:

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 legally marketed predicate 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: K992994
Device Name: The Turbo 7000™ System

Intended Use:

The Turbo 7000™ System's intended use is the cutting and removal of bone and tissue in general ENT, head & neck, and otoneurologic procedures.

Otology procedures would include:
- mastoidectomy and
- mastoidotomy.

Sinus applications would embody:
- septoplasty and
- procedures such as
  - the removal of septal spurs,
  - polypectomy,
  - antrostomy,
  - ethmoidectomy/sphenoethmoidectomy,
  - frontal sinus trephination and irrigation,
  - frontal sinus drill out,
  - endoscopic DCR and
  - trans-spehnoidal procedures.

Nasopharyngeal/Laryngeal procedures would comprise:
- adenoidectomy,
- tracheal,
- laryngeal polyectomy,
- laryngeal lesion debulking and
- tonsillectomy.

Head and neck procedures would encompass:
- soft tissue shaving,
- rhinoplasty (narrowing of the bony vault and revision of the bony pyramid),
- removal of fatty (adipose) tissue (lipo debridement) in the maxillary and mandibular regions of the face, and
- acoustic neuroma removal.

Additionally, an irrigation pump is integrated into the controller unit to provide irrigant in conjunction with the procedures.

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K992994