

510(k) Summary of Safety and Effectiveness

JAN 12 1998

K974232

Trade Name: ESSential® Shaver System
Modification to the ESSential® Sinus Shaver System (K953096)

Common Name: Electrical Surgical Shaver

Classification Name: Surgical ENT drill, electric or pneumatic including handpiece and ENT burr/blades

Official Contact: Deborah Arthur
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Date Prepared: November 11, 1997

The modified ESSential Shaver System is substantially equivalent to the Xomed XPST™ System used with the STRAIGHTSHOT™, PERFORMA™ and SKEETER™ handpieces and the ESSential Shaver System.

The ESSential Shaver System is presently intended for the removal of soft tissue and small amounts of bony obstruction secondary to chronic sinus disease. The modification to this system would expand its intended use to the cutting and removal of bone and tissue in general ENT, head & neck, and otoneurologic procedures. Otolaryngology procedures could 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, laryngeal lesion debulking and tonsillectomy. Head and neck procedures would encompass soft

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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 at the cerebellopontine angle.

The modified ESSential Shaver System that is described in this notification has the same technological characteristics, power modality and mode of operation as the originally cleared device. The broadened intended uses are substantially equivalent to the described predicate Xomed device. The modified ESSential Shaver System is designed to meet UL 2601-1 and IEC 601-1-2.

Differences between the modified ESSential Shaver System and the predicate devices should not affect the safety or effectiveness.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 1998

Deborah A. Arthur
Group Manager
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Re: K974232
Electrical Surgical Shaver
Dated: November 11, 1997
Received: November 12, 1997
Regulatory class: I
21 CFR 874.4140/Procode: 77 EQJ
21 CFR 874.4250/Procode: 77 ERL

Dear Ms. Arthur:

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 requirement, 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Food and Drug Administration
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510(k) Number:

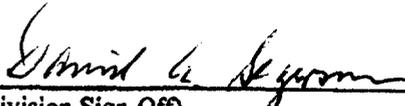
Device Name: ESSential® Shaver System

Modification to the ESSential® Sinus Shaver System (K953096)

Intended Use:

The ESSential Shaver System is presently intended for the removal of soft tissue and small amounts of bony obstruction secondary to chronic sinus disease. The modification to this system would expand its intended use to the cutting and removal of bone and tissue in general ENT, head & neck, and otoneurologic procedures. Otology procedures could 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, 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 at the cerebellopontine angle.

Prescription Use
(Per 21 CFR 801.109)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974232