K981966

AUG 17 1998

Michael M. Knott, M.D.

Michael M. Knott, M.D., Inc.

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Non-Confidential Summary of Safety and Effectiveness

June 3, 1998

Michael M. Knott, MD
355 Rose Pine Court
Tahoe City CA 96145-5577
Tel (530) 583-9371

Official Contact:	Michael M. Knott, MD
Proprietary or Trade Name:	Nosebleed Noseclip
Common/Usual Name:	Noseclip
Classification Name:	Anesthesiology
Predicate Devices:	"Snuffer" – Vacumed, Ventura CA Noseclip – Qosinna, Edgewood NY Noseclip – AMSCO, Pittsburgh PA

Device Description:

Existing respiratory noseclip is to be used to treat simple anterior (front) nosebleeds.

Indicated Use – The treatment of simple anterior (front) nosebleeds.

Environment of Use – Anywhere the device may be safely applied: home, work, school, or hospital.

Patient Population – Adult and children (not for use on infants)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 14 1998

Michael M. Knott, M.D.
P.O. Box 5577
355 Rose Pine Ct.
Tahoe City, CA 96145

Re: K981966
Nosebleed Noseclip
Dated: May 28, 1998
Received: June 4, 1998
Regulatory class: I
21 CFR 874.4100/Procode: 77 EMX

Dear Mr. Knott:

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/dsma/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

SECTION 3

INDICATIONS FOR USE

Pursuant to the Notice of February 6, 1996 regarding listing of Indication for Use on a separate sheet, the following is per that request.

510(k) Number: 981966 (To be assigned)

Device Name: Nosebleed Noseclip

Intended Use: The treatment of simple anterior (front) nosebleeds by application of a noseclip to the external nose in adults and children.
Not for use on infants.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K981966

Prescription Use ____ **or** **Over-the-counter Use** X
(Per CFR 801.109)