3/5/99

K990366

Exmoor Plastics

Your Ref: Our Ref: MB/PAS

Contact: Margaret Blackmore

Date: 28 January 1999

Reference: DMR/1/I/64

SUMMARY OF SAFETY AND EFFECTIVENESS

Trade Name:	Exmoor Suction Clearance Kit
Common Name:	Ear Suction Clearance Kit
Classification Name:	Surgical Instrument Kit, Disposable 79 KDD
Predicate Devices:	Richards Ear Examkit, Exmoor Tympanocentesis Kit (510K 973587), Exmoor Myringotomy Kit (510K 980828)
Description of Device:	Comprehensive, single use, sterile procedure pack comprising: 18 swg fine end 14 swg suction tube Cotton wool mop Wax curette
Intended Use:	This device is intended to clean the external ear canal and tympanum.
Comparison with Predicate Devices:	The component parts of this kit are present in both the Exmoor Tympanocentesis Kit (510K 973587) and the Exmoor Myringotomy Kit (510K 980828). The Richards Ear Examkit is manufactured from very similar stainless steel and plastic, the main difference being the inclusion of aural specula in the Richards kit. Exmoor considered these unnecessary, as they are standard equipment in outpatients departments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 5 1999

Margaret Blackmore
Regulatory Affairs
Exmoor Plastic Ltd.
Lisieux Way, Taunton,
TA1 2LB, U.K. -United Kingdom

Re: K990366
Exmoor Suction Clearance Kit
Regulatory Class: II/21 CFR 874.4420
Product Code: 77 LRC
Dated: January 29, 1999
Received: February 5, 1999

Dear Ms. Blackmore:

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 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. However, you are responsible to determine that the medical devices you use as components in the kit have been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 the 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,

for

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Attachment 4

DMR / 1 / 1 / 6

510(k) Number (if known): K990366

Device Name: EXMOOR SUCTION CLEARANCE KIT

Indications for Use:

The need to clear and clean the external ear canal.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Segmon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K990366

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)