Exmoor
Plastics

K980828

OCT 2 2 1998

Your Ref: Our Ref: MB/PAS/K980828

Contact: Margaret Blackmore

24 July 1998

Ref: K980828

29 JUL 98 10:50

SUMMARY OF SAFETY AND EFFECTIVENESS

Trade Name: Exmoor Myringotomy Kit

Common Name: Myringotomy Kit

Classification Name: Inserter, Myringotomy Tube

Predicate Devices: Richards Set-Op Myringotomy Kit
Cat. No. 89-0205 and 89-0206
Exmoor Tympanocentesis Kit

Description of Device: This single-use device is composed of any combinations of the components included within attachment numbers:

2, 2a, 2b, 2c, 2d, 2e, 2f, 2g, 2h

Note: all kits shall contain a myringotome and an instrument for inserting the ventilation tube/ grommet.

It has been sterilised by gamma irradiation and is ready for use.

* The ventilation tubes have been sterilised by steam.

Intended Use: This procedural device is intended to make a myringotomy incision, aspirate middle ear fluid, and transport and insert aural ventilation tube(s)

Exmoor Plastics Ltd., Lisieux Way, Taunton, TA1 2LB, U.K.
Tel: (01823) 276837 Fax: (01823) 334154

COPY

Co. Reg. No: 2075762 (Eng)

Comparisons with
Predicate Devices:

1. The Richards Set-Op Myringotomy Kit

This is an instrumentation kit, which consists of a curette, a myringotome, an aural ventilation tube inserter and a set of aural specula. (Please see Attachment 7).

The Exmoor Myringotomy Kit is a complete procedure pack with instrumentation similar, but more comprehensive than, the predicate device, including instruments to make a myringotomy incision, to aspirate, to transport and insert aural ventilation tubes, together with fenestrated ear drape, a sterile drape, a dust cover, a mop, a curette, surgical gloves and means of disposing safely of a sharp instrument and a disposal bag.

The materials used for both sets of instruments are essentially the same, being stainless steel and various plastics.

Note: the Attachments 2 through 2k comprise an exhaustive selection list of components, including the elements which make up the sub-assemblies.

2. The Exmoor Tympanocentesis Kit.

This predicate procedure pack comprises many of the same components as the subject Myringotomy Kit, as clarified below:

Component		Present in Predicate (TK/1)	Present in Subject (MK/)
MP180331	Cream Ointment Ear Syringe	x	√
MP180038	White crepe sterilisation paper	√	√
MP180133	Green crepe sterilisation paper	√	√
MP180083	Finex latex gloves	√	√
MP180241/180242	Aural Specula	√	√
MP170714	Mal Mop	√	√
MP180045	Curette	√	√
Various	Single Use Suction Tube	√	√
MP170315/180124	Myringotome/Suction Inserter	√	√
MP180024	Specimen Trap	√	x
Various	Aural Ventilation Tubes	x	√
MP180070	Cotton Wool Swab	√	√
MP180240	Disposal Bag	√	√
MP180062	Disposafe	√	√
MP180148	Moulded Tray	√	√
MP180088	Peel Pouch	√	√

copy

Both the predicate and subject kits are intended to perform myringotomy procedures but differ in that the TK/1 is designed to trap fluids aspirated from the middle ear for infection typing, a diagnostic procedure akin to myringotomy, while the MK/- devices are treatment kits which include myringotomy and allow for the insertion of aural ventilation tubes, if the surgeon should so wish. The former includes a myringotome/suction tube combination, for incising and aspirating via the tympanum, while the latter, being offered in three basic forms, provides:

a) MK/5 a myringotome + suction tube + Pop-Pin inserter instrument. (See Attachment 6c)

b) MK/6 a myringotome + suction tube grommet inserter, in the form of a notched sucker end.

c) MK/7 a myringotome + suction tube ± micro alligator forceps

Please note that both the predicate device and the subject device are packed in the same way, in the same environment, by the same operatives, under the same quality system and are subject to the same rigorous, sealing, bioburden and (AAMI validated) gamma sterilisation processes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 22 1998

Margaret Blackmore
Regulatory Affairs
Exmoor Plastics Ltd.
Lisieux Way, Taunton
TA1, 2LB,
United Kingdom

Re: K980828
Exmoor Myringotomy Kit MK/5, MK/6, and MK/7
Regulatory class: II/21 CFR 874.3880 & 21 CFR 880.6740
Procode: 77 ETD & 80 JOL
Dated: July 24, 1998
Received: July 29, 1998

Dear Ms. Blackmore:

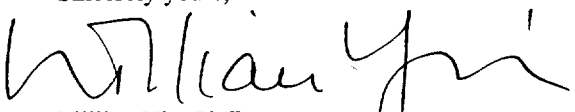
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments 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 either 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.

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,



Lilllian 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

510(k) Number (if known): K980828

Device Name: Exmoor Myringotomy Kit

Indications for Use:

Requirement for myringotomy, with or without the insertion of aural ventilation tube(s).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K980828

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

(Optional Format 1-2-96)

copy