



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 17 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Marcus Tippet
Technical Consultant
Dentsleeve Pty Ltd
56 a/b Cnr St Annes Place & Glen Osmond Road
Parkside, South Australia
AUSTRALIA 5063

Re: K983665
Dentsleeve Manometric Assemblies
Dated: February 9, 1999
Received: February 16, 1999
Regulatory Class: II
21 CFR 876.1725/Procode: 78 KLA

Dear Mr. Tippet:

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/dsma/dsmamain.html>".

Sincerely yours,

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

Enclosure

510(k) number (if known): **K983665**

Device Name: **Dentsleeve Manometric Assemblies**
Product code: **78KLA**

Indications For Use:

Use of Dentsleeve Manometric Assemblies is indicated when measurements of gastrointestinal tract pressures are judged to be useful for determining management of adults, children & infants with proven or suspected gastrointestinal motor disorders.

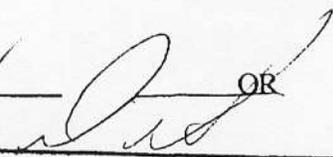
(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use OR
(Per 21 CFR 801.109)

Over-The-Counter Use _____

(Optional Format 1-2-96)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K983665

10 510(k) Summary of safety and effectiveness

Dentsleeve Manometric Assemblies are designed for the monitoring and analysis of gastrointestinal pressures. They are designed to be used in conjunction with a low compliance manometric perfusion pump. The major structures of the Manometric Assemblies is a multi-channeled, medical grade, silicone rubber extrusion.

The Assemblies are designed with variations in length and channel number (depending on the extrusion and application) to enable precise low compliance pressure measurement from most areas of the GI tract. When attached to a manometric perfusion pump, a constant flow of perfusate is perfused into the assembly and into the GI tract of the patient provided the perfusion pump is correctly operated. When the pressure changes within the GI tract the pressure is transferred faithfully up the assembly and detected with external pressure transducers mounted on the manometric perfusion pump.

Indications

Use of Dentsleeve Manometric Assemblies is indicated when measurements of gastrointestinal tract pressures are judged to be useful for determining management of patients with proven or suspected gastrointestinal motor disorders.

Technical Characteristics**Minimisation of discomfort of intubation**

Dentsleeve assemblies are made of silicone rubber. The properties of silicone rubber used by Dentsleeve facilitate the manufacture of smaller diameter (lower compliance) channels. The flexibility of silicone rubber aids patient comfort and the heat tolerance of the material allows autoclaving.

Avoidance of pharyngeal water infusion

Dentsleeve assemblies are suitable for use with air perfusion which is used only in pharyngeal manometry to monitor swallowing.

Testing and safety

The Manometric assemblies have been tested for biocompatibility, functionality and ability to be sterilized up to 50 times by autoclave. All testing results are compiled in attachments A, B & C.

A Risk assessment and Failure Mode Effects and Criticality Analysis, the results of which can be seen in attachment D.

Benefit vs. Risk

The risks of use of a Dentsleeve Manometric Assembly are believed to be minimal, provided this device is operated and maintained as described in the product labelling. Any significant but still minor risks of the use of the device are essentially those associated with gastrointestinal intubation. Proper management of these risks requires the performance or supervision of measurements by individuals who have been adequately trained in methods of gastro-intestinal manometry, including the understanding of methods that ensure safe passage of manometric assemblies safely. Operators of this device must be adequately alert to factors that increase either the risk of perforation during intubation, such as stenoses of the gastro-intestinal tract or other physical deformities, or pulmonary aspiration of refluxed or vomited gastro-intestinal contents