JUL 15 1999

K984528
Premarket Notification

510(k) Summary

Submitted by: Parker Medical

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Date of Summary: March 18, 1999

Name of the Device

Trade names: Parker Flex-Tip Endotracheal Tube
Parker FlexEMS Endotracheal Tube

Common name: Cuffed tracheal tube

Classification name: Tracheal tube

Classification:

Class II, 21 CFR 868.5730

Predicate device:

Kendall Sheridan CF Tracheal Tube (K822082)

Product Description:

The Parker tracheal tubes are sterile, single use devices, for use in anesthesia and emergent and respiratory care where mechanical ventilation is required. The tube will be made in four sizes: 6.5, 7.0, 7.5, and 8.0 mm ID. It is identical to the predicate device in material composition, biocompatibility, packaging, sterilization, and in all structural respects, except for the following features:

(1) Instead of a semi-rigid, side-beveled distal tip, the Parker tube has a flexible, slightly rounded, rear-beveled distal tip which tapers centrally toward the midline of the lesser curvature of the tube.

(2) Instead of a single, lateral Murphy eye opposite the bevel, the Parker tube has two, facing Murphy eyes flanking the bevel.

(3) Instead of a radiopaque stripe on the greater curvature of the tube and a cuff inflation circuit on the lesser curvature of the tube, the positions of these two features are reversed on the Parker tube.

Indications and Usage:

Parker tracheal tubes are designed for oral intubation and are indicated for airway management. Other, reinforced tracheal tubes should be used to reduce the potential for kinking whenever an unusual positioning of the head or neck is to be required following intubation.

Non-clinical Performance Data:

ASTM F1242-96 is widely regarded as a performance standard written to be applicable to "standard" tracheal tubes, such as the predicate device, but not necessarily to all aspects of specialized tubes, such as the Parker tube. Nevertheless, Parker tracheal tubes comply with ASTM F1242-96 in all respects except for the following:

(1) Clause 6.4.1 provides for a tip which is beveled laterally. The predicate device meets this requirement. The Parker tube tip, by design, is beveled posteriorly, toward the greater curvature of the tube, rather than laterally.

(2) Clause 6.5 provides for a Murphy eye on the side of the tube opposite the bevel. The predicate device meets this requirement. The Parker tube tip, by design, has two Murphy eyes, rather than one, and they are placed lateral to, rather than opposite, the bevel.

Note: Clause 4.2.1 provides that the patient end of the tube shall be "rounded without sharp points or rough edges." The predicate device meets this requirement. Although the Parker tube tip is tapered, its point is rounded, rather than sharp, and its edges are also rounded, rather than rough.

Clinical Performance Data:

To determine whether the unique tip design of the Parker tracheal tube would adversely affect its safety or efficacy, both orotracheal and nasotracheal intubations were carried out in adult human cadavers with standard tracheal tubes and with Parker tracheal tubes. These intubations were watched through a videoscope, and some were recorded. In this study, the tip of the Parker tracheal tube appeared to be clearly and consistently less traumatic to the nose, larynx, and trachea than standard tracheal tubes, including the predicate device.

A comparative clinical study of intubation was also carried out with IRB approval and informed consent on 66 adult patients orotracheally intubated for surgery. 31 of those patients were intubated with a standard tracheal tube and 35 were intubated with a Parker tracheal tube. The conclusion drawn from this study was that the Parker tracheal tube is *at least* as safe and efficacious for orotracheal intubation as standard tracheal tubes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 1999

Jeffrey D. Parker, M.D.
Parker Medical
109 Inverness Drive East, Suite J
Englewood, CO 80112-5105

Re: K984528
Parker Flex-Tip Tracheal Tube and Parker FlexEMS Tracheal Tube
Regulatory Class: II (two)
Product Code: 73 BTR
Dated: April 22, 1999
Received: April 22, 1999

Dear Dr. Parker:

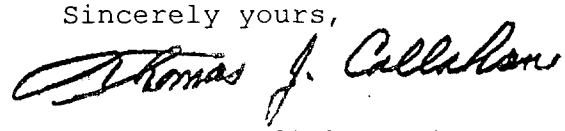
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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) 594-4648. 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER: K984528

DEVICE NAMES: PARKER FLEX-TIP TRACHEAL TUBE
and
PARKER FlexEMS TRACHEAL TUBE

"INDICATIONS AND USAGE"

Parker cuffed tubes are designed for oral intubation and are indicated for airway management.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter-Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____