

510(k) Summary

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Submitted by: Parker Medical, Inc.
9457 S. University Blvd., #331
Highlands Ranch, CO 80126
303-799-1990

Contact Person Lewis Ward
L.W. Ward and Associates, Inc.
4655 Kirkwood Court
Boulder, CO 80301

JUN - 8 2010

Date Prepared: May 10, 2010

Product: Trade Name: Parker Medical Nasal/Flex-Tip Tracheal Tube
Common Name: Tracheal Tube (also, Endotracheal Tube)

Classification
Name: Tube, Tracheal (w/wo connector)

Intended Use: Tracheal tube designed for oral and nasal intubation and indicated for airway management

Technological
Characteristics: The Parker nasal tracheal tubes are sterile, single use devices for use in anesthesia and emergent and respiratory care. The tubes are made of PVC. They are identical in all respects to the predicate Sheridan Catheter Corporation tracheal tubes K822082 for oral and nasal intubation routes for airway management. The tube has a standard 15mm connector on the proximal end to connect to an oxygen source. The distal end has the Parker Flex-Tip formed component, a flexible tip designed to facilitate less traumatic insertion of the tube through the nose or mouth. The tube is marked along the tube to show insertion depth. The tube is designed with or without a distal balloon for securing closure around the inserted tube. Cuffed tubes have a cuff inflation port to allow testing and inflation of the tube. All tubes have a radiopaque line along the full length of the tube. Preformed tubes with an "S" shape are offered to better fit against the face or jaw. Standard tubes are offered that have a curvature to the shape.

Substantial
Equivalence:

The Parker Flex-Tip Nasal Tracheal Tube is an expanded Indication for nasal intubation of the Parker Flex-Tip Tracheal Tube previously cleared under K984528 for oral intubations.

Test Data:

Independent clinical testing of the Parker Flex-Tip Tracheal Tube demonstrates that it significantly minimizes and prevents the nasal trauma and bleeding which commonly occur in nasal intubations performed with comparable, commercially available tracheal tubes.

Conclusion:

The nonclinical and clinical tests demonstrate that the device is as safe, as effective, and performs at least as safely and effectively as the Parker Flex-Tip Tracheal Tube predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Parker Medical Incorporated
C/O Mr. Lewis Ward
Consultant to Parker Medical Incorporated
L.W. Ward and Associates Incorporated
4655 Kirkwood Court
Boulder, Colorado 80301

JUN - 8 2010

Re: K100564
Trade/Device Name: Parker Medical Nasal/Oral Flex-Tip Tracheal Tube
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BTR
Dated: May 13, 2010
Received: May 17, 2010

Dear Mr. Ward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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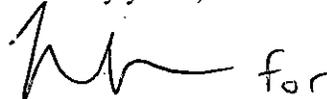
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "A. Watson for".

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Parker Medical Nasal/Oral Flex-Tip Tracheal Tube

Indications for Use:

Tracheal tube designed for oral and nasal intubation and indicated for airway management.

Prescription Use X AND/OR
(Part 21 CFR 801 Subpart D)

Over-the-Counter Use _____
(21 CFR 801 Subpart C)

(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 Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K100564