510(k) Summary K 121378
Page 1 of 3
06-May-2012

JUN 2 1 2012

Prodol Meditec Ltd.
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Zhuhai, 519085 China PR

Official Contact: Tanya Tan – General Manager
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Proprietary or Trade Name: Airtraq® SP – MR
Airtraq® Avant

Common/Usual Name: Rigid Laryngoscope

Classification Name: Rigid Laryngoscope
Product code – CCW
21 CFR 868.5540
Class 1

Predicate Devices: Truphatek Tru-MR™ - K062523

Device Description:
Airtraq® Optical laryngoscope is an anatomical shaped rigid laryngoscope which allows the user to see the airway anatomy during insertion and intubation. It is designed with a guide channel in which one loads the endotracheal tube ("ET tube") that is then advanced once the glottis opening has been identified and centered in the view field of the Airtraq® optics. Prodol Meditec offers two (2) models.

Airtraq® SP – single patient
This model is a completely self-contained unit that operates on standard non-magnetic AAA batteries. It is a single patient use, disposable.

Airtraq® Avant
Avant once assembled is identical in its design and function as the Airtraq® SP model.

Avant is designed as 2 components unlike the Airtraq® SP model.

1. Optics – This is a limited life reusable components which contains the lenses and mirrors of the optical system plus the rechargeable, non-magnetic battery, and PCB which controls the LED light, heater and diagnostics for the battery.
2. Blade – There are 2 blade sizes, Regular (ET tube size 7.0 mm to 8.5 mm) and Small (ET tube 6.0 mm to 7.5 mm). These are single use disposables in which the Optics are inserted and then the assembled device used. There is an eye cap that incorporates a protective lens that fits over the Optics once it has been inserted into the Blade.

510(k) Summary
Page 2 of 3
06-May-2012

Indications for Use:
Airtraq® SP – MR and Airtraq® Avant are intended to facilitate and aid in tracheal intubation in a Magnetic Resonance (MR) environment, not to exceed a 3.0 Tesla static magnetic field.

Patient Population:
Patients who are to be intubated as determined by the clinician.

Environment of Use:
Adding Magnetic Resonance (MR) environments up to 3.0 Tesla strength.

Comparison to Predicates

Features	Truphatek Tru-MR™ K062523	Proposed Device Airtraq® SP –MR Airtraq® Avant
Indications for use	The Tru-MR ™ laryngoscope set is used to facilitate and aid in tracheal intubation in a Magnetic Resonance (MR) environment, not to exceed a 3.0 Tesla static magnetic field.	The Airtraq® SP – MR and Avant are intended to facilitate and aid in tracheal intubation in a Magnetic Resonance (MR) environment, not to exceed a 3.0 Tesla static magnetic field.
Environment of Use	MR environments Not to exceed 3.0 Tesla	Same Not to exceed 3.0 Tesla
Patient Population	Patients to be intubated	Patients to be intubated
Configurations	Handles Battery Blades	Airtraq® SP MR Blade AAA Battery Internal Optics Airtraq® Avant Blade Reusable Optics Rechargeable battery
Performance Testing	ASTM F2052-02 Standard Test Method of Magnetically Induced Displacement Force of Medical devices in the Magnetic Resonance Environment Pass criteria is deflection of < 45 degrees	ASTM F2052-02 Standard Test Method of Magnetically Induced Displacement Force of Medical devices in the Magnetic Resonance Environment Pass criteria is deflection of < 45 degrees

510(k) Summary
Page 3 of 3
06-May-2012

Substantial Equivalence Discussion

The Airtraq® SP – MR and Airtraq® Avant optical laryngoscopes are viewed as substantially equivalent to the predicate device because:

Indications –
- Identical to predicate – K062523
- Intended to facilitate and aid in tracheal intubation in a Magnetic Resonance (MR) environment, not to exceed a 3.0 Tesla static magnetic field.

Technology –
- Similar – handle, battery, blade design to predicate – K062523
- Both devices are Class 1 exempt from PMN

Materials –
- The materials are part of a Class I exempt device.

Environment of Use –
- Identical to predicate – K062523
- Adding Magnetic Resonance (MR) environments up to 3.0 Tesla strength.

Patient Population –
- Identical to predicates – K062523
- Patients who are to be intubated

Performance Testing
- Identical to predicate K062523
- Testing has been performed according to ASTM F2052-02 for deflection in a 3.0 Tesla environment

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

Prodol Meditec Limited
C/O Mr. Paul E. Dryden
Authorized Representative
Airtraq LLC
24301 Woodsage Drive
Bonita Springs, Florida 34134

JUN 21 2012

Re: K121378
Trade/Device Name: Airtraq® SP MR, Airtraq® Avant
Regulation Number: 21 CFR 868.5540
Regulation Name: Rigid Laryngoscope
Regulatory Class: I
Product Code: CCW
Dated: May 6, 2012
Received: May 21, 2012

Dear Mr. Dryden:

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.

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" (21CFR 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,

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 Statement

510(k) Number: K121378 (To be assigned)

Device Name: **Airtraq® SP MR**
Airtraq® Avant

Indications for Use:

Airtraq® SP – MR and Airtraq® Avant are intended to facilitate and aid in tracheal intubation in a Magnetic Resonance (MR) environment, not to exceed a 3.0 Tesla static magnetic field.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultz

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K121378