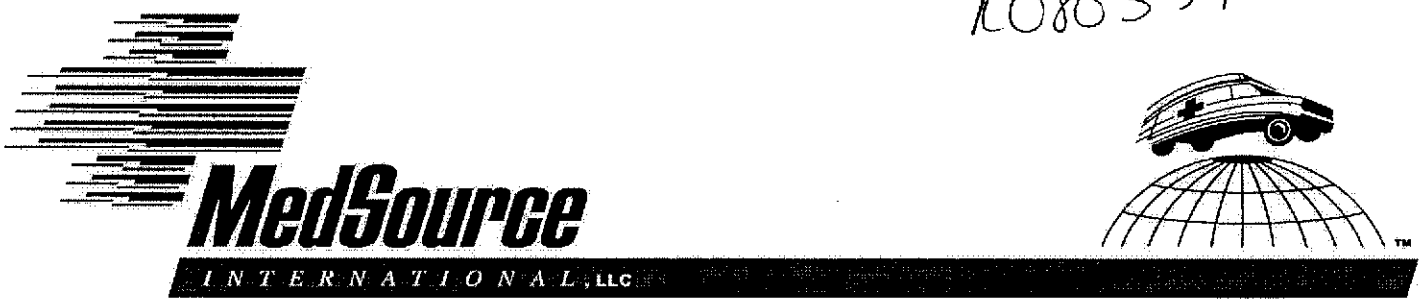
K080339



5346 Shoreline Drive, Mound, MN 55364

SECTION 510(K) Summary

October 26, 2008

This 510(K) Summary of Safety and Effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Submitter's Information: MedSource International, LLC
5346 Shoreline Drive
Mound, MN 55364
O: (952) 472-0131 F: (952) 472-0136
FDA Establishment Registration No.: 3003674698

OCT 27 2008

Contact Person: Howard Cooper
Quality Consultant
EQACT, INC.
317-826-4398 (O)
317-523-2314 (C)
htc@eqact.com

October 26, 2008

Device Names:

Trade/Proprietary Names:	(1) MedSource Endotracheal Tube (with and without cuff), (stylet sold separately)
	(2) MedSource Pre-Loaded Endotracheal Tube and Stylet (Pre-loaded ET Tube with Stylet; with and without cuff).
Common/Usual Name:	Endotracheal Tube; Tracheal Tube; Trach Tube; ET Tube. (with and without connector),(cuffed and uncuffed), (with and without stylet)
Common/Usual Name:	Stylet.

Classifications:

	Endotracheal Tube	Stylet
Panel:	Anesthesiology	Anesthesiology
Regulatory Reference:	21 CFR §868.5730	21 CFR §868.5790
Classification Name:	Tracheal Tube	Tracheal Tube Stylet
Product Code:	BTR	BSR
Device Class	Class II	Class I; 510k Exempt

Description:

MedSource Pre-Loaded Endotracheal Tube (Cuffed & Uncuffed) with and without Stylet:

- Constructed of Polyvinylchloride
- Single lumen tube with or without a cuff;
- Tapered tip with Murphy Eye;
- Clear medical-grade tubing(polyvinyl) with graduations;
- Connector with check valve;
- Pre-loaded with Stylet having a low friction coating;
- Various sizes
- Sterile Single-Use Device

Intended Use:

Indications for Use: MedSource Endotracheal Tube:
The device is intended for oral or nasal intubation and for airway management.

Indications for Use: MedSource Pre-Loaded Endotracheal Tube and Stylet:
The device is intended for oral or nasal intubation and for airway management.

Prescription Use: (21 CFR 801(D)) Yes

Technological Characteristics:

Characteristics	MedSource	Predicate Devices
Materials of Construction	Polyvinyl Chloride	Equivalent
Sizes	Typical product sizes	Same
Method of Use	Manual	Manual
Murphy's Eye	Yes	Yes
Pilot Balloon	Yes	Yes
With & Without Stylet	Yes	Yes

Standards

Standard	Title	Status of Compliance
ISO 5361:1999	ISO 5361:1999, Anaesthetic and respiratory equipment - Tracheal tubes and connectors	Compliant to applicable sections
ISO10993-1 (2nd edition-1997-12-15	Biological Evaluation Of Medical Devices—Part 1: Evaluation and Testing	Compliant to applicable sections per testing

Substantial Equivalence Discussion

Description	MedSource	Predicate Devices
Device	(1) MedSource Endotracheal Tube (with and without cuff), (stylet sold separately) (2) MedSource Pre-Loaded Endotracheal Tube and Stylet (Pre-loaded ET Tube with Stylet; with and without cuff).	K925505; K925506 Rusch™ Flexi-Set® Cuffed ET Tube and Stylet Set K952100 K031794 EndoFlex™ Tracheal Tube K042683 Well Lead™ ET Tube
Intended Use	The device is intended for oral or nasal intubation and for airway management.	Exact or similar wording
Materials of Construction	Polyvinyl Chloride	Equivalent
Single Use/Sterile	Yes	Yes
Murphy's Eye	Yes	Yes
Pilot Balloon	Yes, as applicable to product	Yes, as applicable to product
With & Without Stylet	Yes	Yes
Instructions for Use	Similar or identical wording for all devices	

Conclusion:

Based on the following, it can be concluded that the MedSource Endotracheal Tube is substantially equivalent to the predicate devices listed above:

1. Intended use is the same.
2. Materials of construction or the same or equivalent.
3. Both the MedSource and the predicate devices have product features such as a Murphy's Eye and Pilot balloon.
4. Instructions for use are the same.

Clinical Studies

No clinical studies were conducted for safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 7 2008

MedSource International, LLC
C/O Mr. Howard T. Cooper
President
EQACT, Incorporated
11715 Fox Road, Suite 400-180
Indianapolis, Indiana 46236

Re: K080339
Trade/Device Name: MedSource Endotracheal Tube (with and without Cuff), (Stylet Sold Separately)
MedSource Pre-Loaded Endotracheal Tube and Stylet (with and without Cuff)
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BTR
Dated: September 24, 2008
Received: September 24, 2008

Dear Mr. Cooper:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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. This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
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

SECTION 4

510(k) Number: Initial Submission _____

Device Names:

Common or Usual Names:
Endotracheal Tube; ET Tube; Tracheal Tube; Trach Tube

Proprietary Names:
(1) MedSource Endotracheal Tube
(with and without cuff), (stylet sold separately);

(2) MedSource Pre-Loaded Endotracheal Tube and Stylet
(with and without cuff).

Indications for Use: **MedSource Endotracheal Tube:**
The device is intended for oral or nasal intubation and for airway management.

Indications for Use: **MedSource Pre-Loaded Endotracheal Tube and Stylet:**
The device is intended for oral or nasal intubation and for airway management.

Prescription Use: (21 CFR 801(D)) Yes **Over-the-Counter Use:** (21 CFR 801(C)) No

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: K080339