K102127

Instrumentation Industries, Inc.
We make Respiratory Care Work!

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AUG 27 2010

Date Prepared: July 23, 2010
Contact Person/Submitter: Doris F. Walter
Official Correspondent for Instrumentation Industries, Inc.: Edward C. Horey

SPECIAL 510(k) SUMMARY
for
JEM Endotracheal Tube Changers

Trade Name	JEM 325, JEM 330, JEM 340, JEM 350, JEM 355, JEM 360, JEM 365, JEM 370, JEM 400
Common Name	Changer, Tube, Endotracheal
Classification Name	Accessory to Tracheal Tube
Regulation	21 CFR 868.5730
Purpose of 510(k) submission	This Special 510(k) application is being submitted to notify the FDA of an intended update to the JEM Endotracheal Tube Changers User Instructions to: 1. add ethylene oxide as a validated alternate sterilization method. 2. and to expand the directions and pictorials in the User Instruction to assist our customers in the use of the JEM Endotracheal Tube Changers. At this time, we would also like to notify the FDA that the printing of the JEM Endotracheal Tube Changers is now done at our Bethel Park location.
Predicate Device	No changes are being made to the devices, thus no Predicate Device is listed in this summary. On September 30, 1980, the FDA ruled that there were no similar devices marketed in the US, thus Premarket Notification was not possible. After additional testing, correspondence and review, Premarket Approval of the JEM 400 was issued by the FDA in 1981. In 1999 eight additional sizes of

	JEM tubes were granted approval through a PMA supplement. On December 9, 2004, a letter from the FDA Office of Device Evaluation was received which stated that the JEM Series products were now subject to Class II controls, rather than Class III.
Device Description	The JEM Series Endotracheal Tube Changer consists of an extruded open lumen, imprinted with graduated markings. The graduated markings are used as a guide for the successful replacement of a tracheal tube.
Intended Use of the Device	JEM Series Endotracheal Tube Changers provide a simple, rapid technique for changing endotracheal and orotracheal tubes, with specific inside diameters. JEM Series Endotracheal Tube Changers are intended for single patient use. This device is intended for sale by or on the order of a physician.
Technological Characteristics	The JEM Series Endotracheal Tube Changer consists of an extruded open lumen, imprinted with graduated markings. The length and diameters of the JEM Endotracheal Tube Changers are size specific and are not interchangeable. Each JEM Endotracheal Tube Changer is extruded of high density polyethylene and is designed for a specific size of endotracheal tube as follows: JEM 325 fits 2.5 mm I.D. endotracheal tubes JEM 330 fits 3.0 mm I.D. endotracheal tubes JEM 340 fits 4.0 mm I.D. endotracheal tubes JEM 350 fits 5.0 mm I.D. endotracheal tubes JEM 355 fits 5.5 mm I.D. endotracheal tubes JEM 360 fits 6.0 mm I.D. endotracheal tubes JEM 365 fits 6.5 mm I.D. endotracheal tubes JEM 370 fits 7.0 mm I.D. endotracheal tubes JEM 400 fits 7.5 mm I.D. endotracheal tubes JEM 401 is sold as a package containing one of each of the nine sizes.
Performance	Use of a JEM Endotracheal Tube Changer assists a health professional in safely changing out a used endotracheal tube for a fresh one in just a few minutes.

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

Ms. Doris Walter
Regulatory Affairs/ Quality Assurance Manager
Instrumentation Industries, Incorporated
2990 Industrial Boulevard
Bethel Park, Pennsylvania 15102

AUG 27 2010

Re: K102127
Trade/Device Name: JEM Endotracheal Tube Changers Models JEM 325, JEM 330, JEM 340, JEM 350, JEM 355, JEM 360, JEM 365, JEM 370, JEM 400
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: LNZ
Dated: July 23, 2010
Received: July 29, 2010

Dear Ms. Walter:

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

K102127

Indications for Use

510(k) Number (if known):

Device Name:

JEM Endotracheal Tube Changers
Models JEM 325, JEM 330, JEM 340, JEM 350, JEM 355,
JEM 360, JEM 365, JEM 370, JEM 400

Statement of Indications for Use:

JEM Series Endotracheal Tube Changers provide a simple, rapid technique for changing endotracheal and orotracheal tubes, with specific inside diameters.

JEM Series Endotracheal Tube Changers are intended for single patient use.

This device is intended for sale by or on the order of a physician.

Prescription Use ___√___ And/Or Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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: K102127