JAN 2 6 2012

K113644

Instrumentation Industries, Inc.
We make Respiratory Care Work!

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Date Prepared: 12/9/2011
Contact Person/Submitter: Doris F. Walter
Official Correspondent for Instrumentation Industries, Inc.: Edward C. Horey

SPECIAL 510(k) SUMMARY
for the
BE 409 Pilot Tube Repair Kit

Trade Name	BE 409 Pilot Tube Repair Kit
Common Name	Pilot Tube Repair Kit
Classification Name	Inflatable Tracheal Tube Cuff, Accessory to
Regulation	21 CFR 868.5750
Purpose of 510(k) submission	The BE 409 Pilot Tube Repair Kit is used to repair an endotracheal or tracheostomy pilot tube that no longer maintains cuff inflation pressure. To make the repair, the leaking pilot tube is cut and the needle of the BE 409 is inserted into the cut end of the pilot tube. A syringe is then attached to the inflation port of the BE 409 and the cuff is re-inflated. The BE 409 Pilot Tube Repair Kit, (K973755), has been sold into commerce since its approval in December, 1997, but it never included the syringe that is needed to complete the re-inflation of a repaired cuff. Instrumentation Industries, Inc. wishes to correct this oversight and requests permission to add one 10cc syringe (without needle) to each assembled BE 409 Pilot Tube Repair Kit. Additionally we request permission to change the User Instruction sheet for the BE 409 to update our company information as well as to make some minor changes within the User information.
Predicate Device	No changes are being made to the device, thus no Predicate Device is listed in this summary.

Device Description	The BE 409 Pilot Tube Repair Kit will quickly and effectively restore the integrity of a pilot tube line when the regular pilot tube is accidentally cut or when the inflation port is cracked and does not maintain cuff pressure. This assembly will help prevent the need for costly and potentially dangerous tube replacement. The pilot tube connector will fit the pilot line of tubes 0.032 inch Inside Diameter - 0.050 inch Inside Diameter.
Intended Use of the Device	When the endotracheal or tracheostomy pilot tube no longer maintains cuff inflation pressure, the needle of the BE 409 Pilot Tube Repair Kit is inserted into the cut pilot tube. The cuff can then be re-inflated in the usual manner. Such a repair can deter the need to replace the entire endotracheal or tracheostomy tube because of a damaged pilot tube. This device is intended for sale by or on the order of a physician. The BE 409 Pilot Tube Repair Kit is intended for single patient use.
Technological Characteristics	The BE 409 consists of a swaged needle with molded tab, a length of micro-bore tubing and a catheter with Luer-Lock fitting. A 10cc/mL syringe is now included in the package.
Performance	Use of a BE 409 Pilot Tube Repair Kit assists a health professional in safely repairing an endotracheal or tracheostomy tube that no longer maintains cuff inflation pressure due to a leaky pilot line, thus reducing the need to re-intubate the patient.

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 F. Walter
Regulatory Affairs, Quality Assurance Manager
Instrumentation Industries, Incorporated
2990 Industrial Park
Bethel Park, Pennsylvania 15102

JAN 2 6 2012

Re: K113644
Trade/Device Name: BE 409 Pilot Tube Repair Kit
Regulation Number: 21 CFR 868.5750
Regulation Name: Inflatable Tracheal Tube Cuff
Regulatory Class: II
Product Code: BSK
Dated: January 5, 2012
Received: January 6, 2012

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.

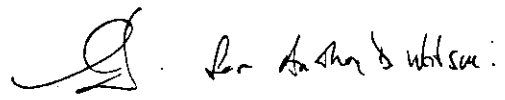
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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



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:

BE 409 Pilot Tube Repair Kit

Statement of Indications for Use:

When the endotracheal or tracheostomy pilot tube no longer maintains cuff inflation pressure, the needle of the BE 409 Pilot Tube Repair Kit is inserted into the cut pilot tube. The cuff can then be re-inflated in the usual manner. Such a repair can deter the need to replace the entire endotracheal or tracheostomy tube because of a damaged pilot tube.

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

The BE 409 Pilot Tube Repair Kit is intended for single patient use.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) And/Or 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: K113644