K133528

JUL 0 3 2014

510(k) Summary

H & H Emergency Cricothyrotomy Tube (cuffed)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

General Information

Submitter Name:	The FDA Group on behalf of: **H & H Associates**
Address:	CAGE 1NNH6 Ordinary, VA 23131
Contact Person:	Paul Harder
Date Prepared:	July 1, 2014

Device Name

Proprietary Name:	Emergency Cricothyrotomy Tube
Common Name:	Cricothyrotomy Tube
Classification Name:	Tracheostomy tube and tube cuff
Device Class:	Class II
Product Code:	JOH
CFR Section:	868.5800

Description

The H & H Emergency Cricothyrotomy Tube is a sterile, single-use cuffed cricothyrotomy tube (airway tube) designed to provide an emergency airway to the patient's lungs when the upper airway/larynx/pharynx or oral & nasal routes are occluded or compromised due to traumatic injury. The outer diameter of the airway tube is 8mm and the inner diameter is 6mm. The inflatable cuff on the airway tube provides a seal against the trachea, ensuring that inspiratory and expiratory gasses are routed through the airway tube and not allowed to escape into the patient's upper airway, thus preventing loss of ventilation as well as protecting against aspiration of stomach contents, blood, and body fluid. The airway tube incorporates a PVC flange 8cm from the distal end, which serves as a positive stop and prevents over insertion of the airway tube and thereby minimizes the likelihood of right main stem bronchial intubation.

Intended Use/Indications for Use

The H & H Emergency Cricothyrotomy Tube is indicated for emergency airway access when conventional endotracheal intubation cannot be performed.
It is intended for adult patients for use in the following environments: Hospital Operating Room, Intensive Care Unit, the Emergency Room or out of the Hospital.

This device is intended for Limited Duration Use (<24 hours).

Predicate Device

K010016 - Cook Melton Emergency Cricothyrotomy Kit (cuffed) cleared 10/9/2001.

Table 1 - Comparison to Predicate Device

Characteristics	*Predicate Device:* **Cook Melker (cuffed) Emergency Cricothyrotomy Kit (K010016)**	*Proposed Device:* **H & H Emergency Cricothyrotomy (cuffed) Kit** (TBD)
Indications for Use	The Melker Emergency Cricothyrotomy (cuffed) catheter is used for emergency access when conventional endotracheal intubation cannot be performed.	H & H Emergency Cricothyrotomy (cuffed) Kit is indicated for emergency airway access when conventional endotracheal intubation cannot be performed. Intended for Limited Duration (<24 hours)
Tube Material	PVC	Same
Cuff Material	PVC	Same
Tube Inner Diameter	5mm	6mm
Tube Outer Diameter	Unknown	8mm
Tube Length	8cm	8cm (flange to tip)
Radiopaque Strip	Yes	Yes
Designed for Percutaneous Entry	Yes	Yes
Provided as Sterile Kit	Yes	Yes
Sterilization	ETO	Gamma
Single Use	Yes	Yes
Packaging	Peel open Tyvek package	5 mil nylon/poly vacuum sealed bag

Non-Clinical Testing

Non-clinical testing was completed to confirm that the device meets all design requirements for functionality, packaging, sterilization, shelf-life and biocompatibility. The H&H Cricothyrotomy Tube met all requirements/clauses of ISO 5366-1:2012.

Table 2 – Non-Clinical Testing

Test	Reference to Standard (If Applicable)	Principle of Test	Acceptance Criteria
Connector Bonding Strength	ISO 5366-1, Section 6.1 Machine end	The security of the attachment of the connector to the tube is tested by applying an axial separation force to the connector	Must be able to sustain axial force of 15 ± 1.5N without movement
Flange (neck-plate) Bonding Strength	ISO 5366-1 Section 6.2 Neck-plate	The security of the attachment of the neck-plate to the tracheosotomy tube is tested by applying an axial separation force to the neck-plate (flange)	Must be able to sustain axial force of 15 ± 1.5N without movement
Connector Fit Test	ISO 5366 Section 5.1	To ensure the connector is compatible with other supporting connectors and devices	The connector's leading edge shall lie between the min and max diam steps of the gauge
Biocompatibility Testing	ISO 10993-1	Testing performed based on mucosal/external communicating contact of limited duration (<24 hrs) to include, Cytotoxicity, Intracutaneous, Sensitization (0.9% NaCl & Cottonseed oil). Hemocompatibilitiy and Acute Systemic testing also completed due to possible blood contact	Must meet requirements outlined in ISO 10993-1 and specified by FDA.

Clinical Data

NA

Summary

All testing demonstrates that the H & H Emergency Cricothyrotomy Tube performs as intended when used in accordance with its labeling.

As the intended use, operating principle, materials and technological characteristics are comparable to the predicate device, the proposed H & H Emergency Cricothyrotomy Tube is substantially equivalent. The minor differences between the proposed device and the predicate device do not raise any new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 3, 2014

H & H Medical Corporation
Mr. Paul Harder
President
4173 George Washington Memorial Highway
Ordinary, VA 23121

Re: K133528
Trade/Device Name: H & H Emergency Cricothyrotomy Tube
Regulation Number: 21 CFR 868.5800
Regulation Name: Tracheostomy tube and tube cuff
Regulatory Class: II
Product Code: JOH
Dated: June 25, 2014
Received: June 26, 2014

Dear Mr. Harder:

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 contact 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. 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,

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Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133528

Device Name: H & H Emergency Cricothyrotomy Tube

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Prescription Use ___X___ (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)

Anya C. Harry -S
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