Hospitech Respiration

510(K) SUMMARY

MAY 3 2013

Hospitech AG Cuffill

510(k) Number K 122721

Applicant's Name: Hospitech Respiration Ltd
20 Hamagshimim Street
Kiryat Matalon,
Petach-Tikva, 49250
Israel.
TEL: 972-3-919-1648,
FAX: 972-3-919-1647

Contact Person: Yoram Levy, Qsite
31 Haavoda St.
Binyamina, Israel 30500
Tel (972)4-638-8837
Fax (972)4-638-0510
Yoram@qsitemed.com

Trade Name: *AG Cuffill* ™

Common Name: Endotracheal cuff pressure regulator

Preparation Date: Aug 31, 2012

Classification: **Classification Name:** cuff, tracheal tube, inflatable
Product Code: BSK
Regulation No: 21 CFR 868.5750
Class: II
Classification Panel: Anesthesiology

Device Description:

The *AG Cuffill* is a disposable hand held measuring device intended to measure and manually regulate intra-cuff pressure of Endotracheal, Tracheotomy and LMAs tubes. *AG Cuffill* is configured as a syringe and consists of a sensitive pressure gauge

embedded within the syringe plunger. ***AG Cuffill*** is battery powered. ***AG Cuffill*** is intended for one patient; it is limited to 100 operations and can be cleaned with disinfectant.

Intended Use Statement:

The ***Hospitech AG Cuffill*** is intended to measure and regulate the intra-cuff pressure of endotracheal tubes, Tracheotomy tubes and Laryngeal Masks Airways (LMAs).

The ***Hospitech AG Cuffill*** is used under medical supervision in hospitals, pre-hospital (EMS), extended care facilities and outpatient clinics, where a patient may be intubated.

Predicate Devices: Substantial equivalence to the following predicate device is claimed:

Device Name	510k No	Date of Clearance
Posey Cufflator	K912723	July 20 1991
CuffAlert	K081805	Nov 14 2008
Easy Cuff	K102704	March 10 2011
PYTON	K092733	Feb 26 2010

Performance Standards

AG Cuffill complies with the following standards:

1. IEC 60601-1:2005/2006 Medical electrical Equipment -- Part 1: General requirements for safety.
2. IEC 60601-1-2:2004 Medical electrical equipment -- Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests.
3. IEC 60601-1-6:2006, Medical Electrical Equipment -- Part 1-6: General requirements for basic safety and essential performances - Collateral Standard: Usability.

4. ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.

Non clinical Performance Testing

The following performance tests were conducted:

#	Name of test	References	Results
1	Design Verification	AG Cuffill Design Verification	The test results show that the AG Cuffill design is according to the specification.
2	Accuracy Verification Performance Test	AG Cuffill Accuracy Verification Performance Test	The test shows that the accuracy of the AG Cuffill throughout its life time at different pressure measurements is within ±1 mmHg.
3	ATP Acceptance Test	AG Cuffill ATP Acceptance Test protocol	The Acceptance Test Protocol is the manufacturing test to be performed to each item before packaging
4	Comparison Test with predicate device	AG Cuffill Pressure Accuracy Performance vs. Posey Cufflator predicate device	AG Cuffill accuracy is within its specifications and is better than the Posey Cufflator

Performance testing demonstrated that the ***AG Cuffill*** meets its specifications and is as safe and effective as the cleared predicate devices.

Materials and Biocompatibility

The ***AG Cuffill*** or the air pumped from it does not come in direct or indirect contact with the patient or the user. Therefore according to ISO 10993-1 there is no need for these parts to be biocompatible.

Comparison to the Predicate Devices and substantial Equivalence

The intended use of the ***AG Cuffill*** is identical to the intended use of its predicate devices.

All predicates, similar to the ***AG Cuffill***, are designed to measure and regulate intracuff pressure.

The device principle of operation and technology of the ***AG Cuffill*** is similar to that of its predicate devices. The structural differences between the ***AG Cuffill*** and its predicate devices do not raise any new questions of safety or efficacy. Moreover, the performance testing and usability study demonstrated that the ***AG Cuffill*** is as safe and effective and performs as well as or better than the predicate devices. Thus, the ***AG Cuffill*** is substantially equivalent to its predicate devices.

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

May 3, 2013

Hospitech Respiration Limited
C/O Mr. Yoram Levy
Qsite
31 Haavoda Street
Binyamina, Israel 30500

Re: K122721
Trade/Device Name: AG Cuffill
Regulation Number: 21 CFR 868.5750
Regulation Name: Inflatable Tracheal Tube Cuff
Regulatory Class: II
Product Code: BSK
Dated: April 17, 2013
Received: May 1, 2013

Dear Mr. Levy:

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,

Kwame O. Ulmer -S FDA for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Hospitech Respiration

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): **K122721**

Device Name: ***AG Cuffill***

Indications for Use:

The ***Hospitech AG Cuffill*** is intended to measure and regulate the intra-cuff pressure of Endotracheal tubes, Tracheotomy tubes and Laryngeal Masks Airways (LMAs) (supraglottic airways).

The ***Hospitech AG Cuffill*** is used under medical supervision in hospitals, pre-hospital (EMS), extended care facilities and outpatient clinics, where a patient may be intubated.

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)

(Division Sign-off)
Division of Anesthesiology, General Hospital, Infection Control and Dental Devices
510(k) Number

Lester W. Schultheis Jr
2013.05.03 16:50:43 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices
510(k) Number: K122721