APPENDIX B

MAY 25 2012

510(K) Summary
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March 28th, 2012

K 112915

Spiritus Technologies LLC
12005 W. 100th Terrace
Lenexa, KS 66215

Tel: 913-205-5493

Official contact:	Brandon Close, President
Proprietary or Trade Name:	Spiritus Cuff Inflation Syringe (SCIS)
Common / Usual Name:	Cuff Inflation Syringe, Accessory
Classification Name:	Inflatable Tracheal Tube Cuff (accessory) BSK – 868.5750
Predicate Devices:	Posey Cufflator® - K912723 Mallinckrodt Tracheal Tube Cuff – K885216 Mallinckrodt Lanz Tracheal Tube Cuff – K791045

Device Description:

The Spiritus Cuff Inflation Syringe (SCIS) is a disposable syringe that will initially inflate the cuff on an endotracheal tube (ETT) to a pressure of 79 cmH2O ± an average standard deviation of 9 cmH2O to create a proper seal with the patients trachea and then automatically decrease the pressure in the cuff to a final pressure of 25cm H2O ± an average standard deviation of 2 cmH2O. The SCIS is designed in the form of a syringe to reflect current practice of using a syringe to inflate the cuff. The device is made of medical grade ISO approved plastic material. The SCIS is intended as a single patient use disposable device.

Indications for Use:	The SCIS will be used to inflate to 25cmH2O ± an average standard deviation of 2 cmH2O the cuff of a high-volume, low-pressure endotracheal tube that has been intubated by a trained medical professional.
Patient Population:	Patient who is to be intubated.
Environment of Use:	It will be used under medical supervision in hospitals, pre-hospitals (Emergency Medical Services), hospital emergency rooms and intensive care units, extended care facilities, and out-patient clinics where patients may be intubated.
Contraindications:	Tracheal tubes designed for pediatric patients or bronchial cuffs of double lumen tubes.

Summary of Technological Characteristics SCIS™ and Predicate Devices

Spiritus Cuff Inflator Syringe – SCIS – Comparison to Predicate Products

ETT Cuff Inflator (accessory) Attributes	**SCIS™**	**Cufflator®**	**Mallinckrodt Hi-Lo Tracheal Tube**	**Mallinckrodt Hi-Lo Lanz Tracheal Tube (510k ref: GV-10 Lanz Pressure Valve)**
Indications for Use (summary)	Inflates tracheal tube cuff to pressure of 25±2 cmH2O	Inflates/deflates and monitors inflatable tracheal tube cuff pressure	Patient airway management (tracheal tube)	-Patient airway management (tracheal tube) -Inflates and regulates inflatable tracheal tube cuff pressure (Lanz valve)
Classification/Regulation/ Code	BSK - Inflatable Tracheal Tube Cuff (accessory)	BSK - Inflatable Tracheal Tube Cuff (accessory)	BSK - Inflatable Tracheal Tube Cuff (accessory)	BTR - Tube, Tracheal (w/wo connector)
510(k) Number	K112915	K912723	K871204	K791045
Patient Population	Intubated patients – single patient - disposable	Intubated patients - reusable	Intubated patients – single patient - disposable	Intubated patients – single patient - disposable
Single patient, disposable	YES	NO	YES	YES
Environments of Use	Under medical supervision in hospitals, pre-hospitals (EMS), emergency rooms (ER), extended care facilities, out-patient clinics where patient may be intubated.	Under medical supervision in hospitals, pre-hospitals (EMS), emergency rooms (ER), extended care facilities, out-patient clinics where patient may be intubated.	Under medical supervision in hospitals, pre-hospitals (EMS), emergency rooms (ER), extended care facilities, out-patient clinics where patient may be intubated.	Under medical supervision in hospitals, pre-hospitals (EMS), emergency rooms (ER), extended care facilities, out-patient clinics where patient may be intubated.
Final Cuff Inflation Pressure	25±2 cmH2O	0 to 120 cmH2O (set by user)	Not Specified	26±2 cmH2O
Precision of Cuff Pressure Measurement	±2 cmH2O*	± 3.8 cmH2O	Not Specified	±2 cmH2O
Establishing final pressure	Automatically set by device mechanical design	Manually set by user	Manually set by user	Automatically set by device mechanical design
Power	Manual	Manual	NA	Manual
Contraindications	None	None	None	None

*Average Standard Deviation

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February 10th, 2012

The Spiritus Cuff Inflation Syringe, SCIS, is viewed as substantially equivalent to the predicate devices listed below:

Posey Cufflator (K912723) - Both the Cufflator and SCIS are cuff inflation devices used in medical environments where patients are intubated. Both devices are used to temporarily inflate the cuff to elevated pressures between 60-90 cmH20 to seat the cuff against the patient's trachea; both devices utilize valves to drop this elevated pressure down to 22-32 cmH2O. Whereas the Cufflator user sets these pressures manually by referring on the Cufflator instruction manual, the SCIS device establishes high and low cuff pressures automatically (79 cmH2O ± an average standard deviation of 9cm and 25 cmH2O ± and average standard deviation of 2cmH2O respectively). SCIS does not monitor pressure as does the Cufflator, yet the SCIS instruction manual calls for the subsequent use of Minimum Occluding Volume and Minimum Leak techniques in conjunction with an intra-cuff pressure measuring device.

Mallinckrodt Hi-Lo Tracheal Tube (K871204) – The materials found in the cuff inflation valve of the Hi-Lo Tracheal Tube include a stainless steel spring, a plastic housing, and a rubber gasket; these materials are substantially equivalent to those present in SCIS. Furthermore, the instruction manual for the Hi-Lo Tube calls for the use of a standard syringe to inflate the Hi-Lo cuff. Since SCIS functions as a syringe, this procedure is substantially equivalent.

Mallinckrodt Hi-Lo Tracheal Tube with Lanz Pressure Valve (K791045) – Both the Lanz valve and SCIS are used to automatically inflate the cuff to a specific pressure. Furthermore, the final cuff pressures left by Lanz and SCIS are substantially equivalent (26 cmH2O ± an average standard deviation of 2 cmH2O and 25cmH2O± an average of 2cmH2O respectively). Lastly, the instruction manual of the Hi-Lo Lanz Tracheal Tube, like that of the Hi-Lo Tube, calls for the use of a standard syringe to inflate the Hi-Lo cuff.

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

Mr. Brandon W. Close
President
Spiritus Technologies, LLC
12005 West 100th Terrace
Lenexa, Kansas 66215

MAY 25 2012

Re: K112915
Trade/Device Name: Spiritus Cuff Inflation Syringe (SCIS)
Regulation Number: 21 CFR 868.5750
Regulation Name: Inflatable Tracheal Tube Cuff
Regulatory Class: II
Product Code: BSK
Dated: May 14, 2012
Received: May 15, 2012

Dear Mr. Close:

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

[redacted]

Indications for Use Statement

510(k) Number: K112915

Device Name: Spiritus Cuff Inflation Syringe (SCIS)

Indications for Use:

The SCIS will be used to inflate to 25±2 cmH2O the cuff of a high-volume, low-pressure endotracheal tube that has been intubated by a trained medical professional.

Patient Population:

Patient who is to be intubated.

Environment of Use:

It will be used under medical supervision in hospitals, pre-hospitals (Emergency Medical Services), hospital emergency rooms and intensive care units, extended care facilities, and out-patient clinics where patients may be intubated.

Prescription Use **XX** **or** Over-the-counter use __

(Part 21 CFR 801 Subpart D) **(21 CFR 807 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: K112915