



Food and Drug Administration
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January 29, 2016

Hamilton Medical AG
Steffen Boden
Regulatory Affairs/Quality Engineer
Via Crusch 8, 7402 Bonaduz
Switzerland

Re: K150893
Trade/Device Name: IntelliCuff
Regulation Number: 21 CFR 868.5750
Regulation Name: Inflatable Tracheal Tube Cuff
Regulatory Class: II
Product Code: BSK
Dated: December 18, 2015
Received: December 28, 2015

Dear Mr. Boden,

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
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Erin I. Keith, M.S.
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Enclosure

INTELLICUFF - 510(K) SUBMISSION

510(k) Summary

510(k) SUMMARY

I. Submitter

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Contact person: Mr. Steffen Boden, Quality Engineer / Regulatory Affairs
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Preparation date: January 28, 2016

II. Device

(Trade) Name of Device:	IntelliCuff
Common or Usual Name:	Cuff Pressure Controller
Classification Name:	Cuff, Tracheal Tube, Inflatable (21 CFR 868.5750)
Regulatory Class:	II
Product Code:	BSK

III. Predicate Device(s)

Primary Predicate Device

ARM MEDICAL DEVICES, INC
PYTON Cuff Regulator; K092733

This predicate has not been subject to a design-related recall

Reference Device

Hamilton Medical AG
HAMILTON-G5; K103803, K131774

This reference device has been subject to a design-related recall: Recall Number Z-1185-2012.

The recall was not related to the cuff pressure controller component to which the IntelliCuff device is compared to.

IV. Device Description

The IntelliCuff device continuously measures and automatically maintains cuff pressure during mechanical ventilation of adults, pediatrics, and neonates using a cuffed endotracheal tube or tracheostomy tube. It is an integrated and continuous cuff pressure control solution that secures airway management in intensive care units, operating rooms, and during interhospital transport.

When the IntelliCuff device is connected to a Hamilton Medical ventilator, cuff pressure settings can be manually adjusted by either selecting the appropriate values on the ventilator or the cuff pressure controller.

It is designed for immediate use; no calibration or maintenance is required. It operates in the recommended range of desired cuff pressures for various cuffed endotracheal tubes to provide suitable solutions for various clinical patient situations. For inflation, room air is used and no contact to the respiratory gas system of a patient occurs. A large-scale display and convenient and intuitive interaction buttons maximize safe use and visibility of all important data.

The associated accessories include:

- Cuff Pressure Tube with Filter
- Device Mount Solution
- USB Power Supply and Car Adapter

V. Indications for Use / Intended Use

The IntelliCuff device is intended to continuously measure and automatically maintain the user-set cuff pressure of an endotracheal tube (ETT) or tracheostomy tube (TT) during mechanical ventilation.

The device can be used with any mechanical ventilator, as follows:

- When used with a non-Hamilton Medical ventilator, IntelliCuff adjusts the cuff pressure to values set on the device.
- When used with a Hamilton Medical ventilator, IntelliCuff adjusts the cuff pressure to values set either on the device or on the ventilator, depending on configuration.

The device is to be used during ventilation of adults, pediatrics, and neonates, who are intubated with ETT or TT, in the following areas:

- In the intensive care ward or in the recovery room
- In the operation room during intubation narcosis
- For emergency medical care or primary care
- During transport within and outside of the hospital
- During transfer by rescue vehicles, ship, jet, or helicopter

VI. Comparison of Technological Characteristics with the Predicate Device(s)

The application of set pressure to seal a cuffed endotracheal tube or tracheostomy tube including the supervision and maintenance of a set cuff pressure is the technological principle for both the subject and predicate devices.

The indication statements for the IntelliCuff device are comparable to those for the predicate devices.

Technological characteristics and performance specifications of the IntelliCuff device are substantially equivalent to those of the predicate devices. At a high level, the subject and predicate devices are based on the following same technological elements:

- Inflation and Deflation of an endotracheal tube or tracheostomy tube
- User-controlled set pressure
- Software-controlled pressure supervision and automatic pressure adjustment
- Use of ambient / room air
- Alarm system
- Battery backup power

The following technological differences exist between the subject and predicate devices:

- Use of an additional pressure sensor
- The primary predicate device is an ICU ventilator with build-in cuff pressure adjustment functionality whereas the subject device is a portable device for cuff pressure adjustment only

Hamilton Medical has demonstrated the IntelliCuff device to have adequate performance. The IntelliCuff device is considered to be substantially equivalent to currently marketed predicate devices that have been previously cleared by FDA.

VII. Performance data

The following performance data were provided in support of the substantial equivalence determination.

Electrical safety and Electromagnetic Compatibility

Electrical safety and EMC testing were conducted on the IntelliCuff device, consisting of the cuff pressure controller and power supply. The device complies with the IEC 60601-1 standard for safety and the IEC 60601-1-2 standard for EMC.

Additional testing

A Human Factors / Usability Study was conducted and the IntelliCuff device was found to be in conformance with the '*Draft Guidance for Industry and Food and Drug Administration Staff - Applying Human Factors and Usability Engineering to Optimize Medical Device Design*'. Additional testing on the IntelliCuff device was conducted according to IEC 60601-1-8, IEC 62366, IEC 60601-1-6 and IEC 62304 standards. Furthermore, a control system analysis was conducted and compliance with applicable clauses of IEC 60601-1-10 was demonstrated. The test results show that the device has adequate performance for its intended use.

FAA Regulations

In accordance with the US Department of Transportation (DOT) and the Federal Aviation Administration (FAA) along with their rules on the 'Use of Respiratory Assistive Devices on Aircraft', the IntelliCuff device meets the applicable safety requirements for Medical Portable a + Electronic Devices (M-PED) by not exceeding the maximum level of radiated radio frequency interference as described in the RTCA/DO 160G, Section 21, Category M.

Mechanical testing

Mechanical safety testing was conducted on the IntelliCuff device. The system complies with the IEC 60601-1 standard for safety and RTCA DO-160G Sect. 8, Cat. R and Cat. U, and Sect. 7 Cat. B.

Software Verification and Validation Testing

Software verification and validation testing was conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a 'major' level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

The results of the software verification and validation testing demonstrate that all specified requirements have been implemented correctly and completely.

Summary

Based on the non-clinical performance as documented, the IntelliCuff device was found to have an adequate performance profile that is similar to the predicate devices.

VIII. Conclusion

The non-clinical test results show that the IntelliCuff device has adequate performance for its intended use and the device performs as intended in the specified use conditions. The hardware and software verification and validation support a determination of substantial equivalence. In addition, the conclusions drawn from the non-clinical tests demonstrate that the device is as safe, as effective, and performs just as well as the predicate devices.