Tianjin Medis Medical Device Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, China, 200120

Re: K182548
Trade/Device Name: Accucuff Cuff Pressure Indicator
Regulation Number: 21 CFR 868.5750
Regulation Name: Inflatable Tracheal Tube Cuff
Regulatory Class: Class II
Product Code: BSK
Dated: September 7, 2018
Received: September 17, 2018

Dear Diana Hong:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Todd D. Courtney -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182548

Device Name
Accucuff Cuff Pressure Indicator

Indications for Use *(Describe)*
The Accucuff Cuff Pressure Indicator is intended to monitor intra-cuff pressures of endotracheal, supraglottic airways or tracheostomy tubes. The device is indicated for the patients from pediatric to adult who have an artificial airway and for which the user would like to monitor cuff pressure.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K182548

1. Date of Preparation: 12/26/2018

2. Sponsor Identification

Tianjin Medis Medical Device Co., Ltd.
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3. Designated Submission Correspondent

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4. Identification of Proposed Device

Trade Name: Accucuff™ Cuff Pressure Indicator
Common Name: Cuff Pressure Indicator

Regulatory Information

Classification Name: Cuff, Tracheal Tube, Inflatable
Classification: II;
Product Code: BSK
Regulation Number: 21CFR 868.5750
Review Panel: Anesthesiology

Device Description

The Accucuff™ Cuff Pressure Indicator is intended to monitor the cuff pressure of endotracheal, supraglottic airways or tracheostomy tubes. It is designed with different color coded zones to indicate the normal, negative and positive pressure. The black marker on the device will be moved when the cuff pressure is changed. The device is available in 10-20 cmH_2O, 20-29 cmH_2O and 40-60 cmH_2O three different models to accommodate the intended populations from pediatric to adult.

Intended Use Statement:

The Accucuff™ Cuff Pressure Indicator is intended to monitor intra-cuff pressures of endotracheal, supraglottic airways or tracheostomy tubes. The device is indicated for the patients from pediatric to adult who have an artificial airway and for which the user would like to monitor cuff pressure.

5. Identification of Predicate Devices

Predicate Device 1
510(k) Number: K142103
Trade Name: Cuff Pilot™

Predicate Device 2
510(k) Number: K102704
Trade Name: Easy Cuff™

Table 1 Comparison of Technology Characteristics

Item	Proposed Device	Predicate Device 1 K142103	Predicate Device 2 K102704
Product Code	BSK	BSK	BSK
Regulation Number	868.5750	868.5750	868.5750
Class	CLASS II	CLASS II	CLASS II
Intended Use	The Accucuff™ Cuff Pressure Indicator is intended to monitor intra-cuff pressures of endotracheal, supraglottic airways or tracheostomy tubes. The device is indicated for the patients from pediatric to adult who have an artificial airway and for which the user would like to monitor cuff pressure.	To monitor intra-cuff pressures of supraglottic airways Patient population: Patients who have an artificial airway and for which the user would like to monitor cuff pressure, pediatric to adult. Environment of Use To be used under medical supervision in hospitals, pre-hospital (EMS), extended care facilities and outpatient clinics, where a patient may have an artificial airway. It may also be used in MRI suites when attached to airways that are MR conditional or MR Safe.	To inflate cuffs and to measure and monitor intra-cuff pressures of endotracheal, supraglottic airways, or tracheostomy tubes. Patient population: Patient who are intubated. Environment of use To be used under medical supervision in hospitals, pre-hospital (EMS), extended care facilities and outpatient clinics, where a patient may be intubated
Range of measured pressure	AC0100P: 10~20cm H_2O AC0100B: 20~29cm H_2O AC0100R: 40~60cm H_2O	0~80cm H_2O	0~30cm H_2O
Pressure accuracy	10~20cm H_2O :+/-2cm H_2O 20~29cm H_2O: +/-2cm H_2O 40~60cm H_2O: +/-4cm H_2O	+/-5cm H_2O up to 80cm H_2O	+/-5% H_2O up to 30cm H_2O +/-0.5cm H_2O up @ 10cm H_2O +/-1cm H_2O up @ 20cm H_2O +/-1.5cm H_2O up @ 30cm H_2O
Pressure indication	Black mark that move with changes in	Bellows that move with changes in pressure	Bellows that move with changes in

method	pressure		pressure
Types of airways to which it can be used	Supraglottic airway Endotracheal tube Tracheostomy tube	Supraglottic airway	Supraglottic airway Endotracheal tube Tracheostomy tube
Sterile	EO sterilization, 10^{-6}	Non-sterile, sterile	Non-sterile
Single Use	Single Use	Single Use	Single Use
Material	Polycarbonate (PC); Silicone	Unknown	Unknown
Biocompatibility			
Cytotoxicity	No cytotoxicity	Conform with ISO 10993 requirements	Conform with ISO 10993 requirements
Skin Sensitization	No skin sensitization		
Irritation	No irritation		

Intended Use

The proposed device has the indication of monitoring intra-cuff pressures of endotracheal and tracheostomy in addition to monitoring the pressure of supraglottic airway compared with the predicate device K142103. However, the two additional indications are covered by predicate device K102704. Therefore, this difference does not raise different safety and effectiveness questions.

Pressure Range

The range of measured pressure for proposed device is different from the predicate devices individually compared. The proposed device is available in three different pressure ranges. However, pressure range compared with both predicate devices falls within the specifications of the predicates cleared previously.

Pressure Accuracy

The pressure accuracy for proposed device is difference from predicate devices. Although the pressure accuracy for proposed device is less than

predicate device K102704, the proposed device has a more precise accuracy than predicate device K142103. Therefore, the accuracy difference does not raise different safety and effectiveness questions.

Airway Type

The type of airway for which the proposed device is indicated is different from predicate device K142103. The proposed device has the additional airway of monitoring endotracheal tube and tracheostomy tube which are identical to predicate device K102704.

Sterilization

The proposed device is provided sterile which is different from the two predicate devices. However, the sterilization method is established and validated per ISO 11135, which ensures the effectiveness of sterilization.

Material

The biocompatibility test (per ISO 10993) has been performed on the proposed device. The results do not show any adverse effect, which demonstrates biocompatibility of the proposed device.

6. Non-Clinical Test Summary

Non-clinical tests were conducted to verify that the proposed device met all the design specifications to establish Substantial Equivalence (SE) with the predicate devices. Test items include:

Conical fitting Performance Test
Pressure Accuracy Test
Repeatability Pressure Accuracy Test
Pressure Accuracy Test exposure to cold and hot temperature
Simulated Transportation Test
Package Integrity Test
Pressure Accuracy and Package Integrity after Accelerated Aging

The test results demonstrate that the proposed device complies with the following standards:

- ISO 594-1:1986 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment-Part 1: General requirement
- ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity;
- ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization;
- ASTM F88/F88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials.
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is Substantially Equivalent (SE) to the predicate devices.