September 6, 2019

Jiangxi Yikang Medical Instrument Group Co., Ltd
Nicholas Su
Regulatory Affairs Specialist
188 Aihua Road, Jinxian County
Nanchang, 331725 Cn

Re: K190213
Trade/Device Name: Yikang Endotracheal Tube
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: Class II
Product Code: BTR
Dated: August 2, 2019
Received: August 12, 2019

Dear Nicholas Su:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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 Courtney
Assistant Director
DHT1C: Division of ENT, Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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)*
K190213

Device Name
Yikang Endotracheal Tube

Indications for Use *(Describe)*
The device is intended for oral or nasal intubation and for airway management.

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.

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510(k) Summary
(as requested by 21 CFR 807.92)
K190213

Submitter of 510(k): Jiangxi Yikang Medical Instrument Group Co., Ltd
Address: 188 Aihua Road,Jinxian County, Nanchang, Jiangxi, China 331725
Phone: +86 791 8563 2226
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Contact Person: Nicholas Su
Regulatory Affairs Specialist
E-mail: andy_smith@yeah.net

Date of summary: January 29, 2019

Proposed device:

Trade Name:	Yikang Endotracheal Tube
Common Name:	Endotracheal Tube
Classification Name:	Tracheal tube
Product Code:	BTR
Panel:	73(Anesthesiology)
Classification:	Class II
Regulation Number:	868.5730

Legally Marketed Predicate Device:

Trade Name:	Well Lead Endotracheal Tube
510(k) Number:	K042683
Submitter of 510(k)/holder:	Well lead Medical Instruments Ltd.

Device Description:
Yikang endotracheal tube is a device intended for oral or nasal intubation and for airway management. It is a sterile and single use device, it is made from medical grade PVC. The Yikang endotracheal tube has cuffed and uncuffed, and is available in size I.D. 2.0mm through I.D. 10.0mm, and has a Murphy eye. It basically consists of tube shaft, cuff, inflation line, pilot balloon, one-way valve, and a male 15mm conical connector. A radiopaque line is incorporated into the full length of the tracheal tube.

When used tracheal tube is inserted through the larynx into the trachea to convey gases to and from the trachea. Cuffed tracheal tube is intended to seal and protect aspiration of secretions, and to provide an unobstructed airway in patients during ventilation. A radiopaque line helps to

determine proper placement of the tracheal tube with the characterization of visibility of tracheal tube in X-rays.

Size I.D. 2.0mm through 4.5mm are intended for pediatric use (12 years old to less than 21years old), Size I.D. 5.0mm through 10.0mm are intended for adult use.

Intended Use:
The device is intended for oral or nasal intubation and for airway management.

Device Performance:
Testing results indicated that the product meets specified performance requirements, and complied with ISO5361:2016.

Comparison of Technological Characteristics:
Yikang's endotracheal tube has the same technological characteristics as the predicate device. The design, material, form, fit, function and method of operation are similar.

Substantial Equivalence

Element of Comparison		Submission Device	Predicate Device K042683	Comparison
Intended Use		The device is intended for oral or nasal intubation and for airway management.	The device is intended for oral or nasal intubation and for airway management.	Same
Principle of Operation		Normal	Normal	Same
Type		Oral/nasal cuffed, Oral/nasal uncuffed, Nasal cuffed, Nasal uncuffed, Oral cuffed, Oral uncuffed.	Oral/nasal cuffed, Oral/nasal uncuffed, Nasal cuffed, Nasal uncuffed, Oral cuffed, Oral uncuffed.	Same
Size		Oral/nasal cuffed (I.D 2.0-10.0)	Oral/nasal cuffed (I.D 5.0-10.0)	Similar
		Oral/nasal uncuffed (I.D 2.0-10.0)	Oral/nasal uncuffed (I.D 2.0-10.0)	Same
		Nasal cuffed (I.D 3.0-10.0)	Nasal cuffed (I.D 5.0-10.0)	Similar
		Nasal uncuffed (I.D 3.0-10.0)	Nasal uncuffed (I.D 2.0-10.0)	Similar
		Oral cuffed (I.D 3.0-10.0)	Oral cuffed (I.D 5.0-10.0)	Similar
		Oral uncuffed (I.D 3.0-10.0)	Oral uncuffed (I.D 2.0-10.0)	Similar
Tube Length	I.D	Oral/nasal cuffed ±5mm	Oral/nasal cuffed ±3mm	/
	2.0	170	/	Meet requirements of
	2.5	170	/	
	3.0	190	/	

	3.5	215	/	ISO5361:2016
	4.0	215	/	
	4.5	240	/	
	5.0	265	245	Similar, and meet requirements of ISO5361:2016.
	5.5	275	275	
	6.0	285	285	
	6.5	305	295	
	7.0	310	310	
	7.5	315	315	
	8.0	330	330	
	8.5	330	330	
	9.0	330	330	
	9.5	330	330	
	10.0	330	330	
	I.D	Oral/nasal uncuffed±5mm	Oral/nasal uncuffed ±3mm	/
	2.0	170	140	Similar, and meet requirements of ISO5361:2016.
	2.5	170	145	
	3.0	190	165	
	3.5	215	185	
	4.0	215	210	
	4.5	240	225	
	5.0	265	245	
	5.5	275	275	
	6.0	285	285	
	6.5	305	295	
	7.0	310	310	
	7.5	315	315	
	8.0	330	330	
	8.5	330	330	
	9.0	330	330	
	9.5	330	330	
	10.0	330	330	
	I.D	Nasal cuffed,±5mm	Nasal cuffed, ±3mm	/
	2.0	/	/	/
	2.5	/	/	/
	3.0	290	/	Meet requirements of ISO5361:2016.
	3.5	290	/	
	4.0	310	/	
	4.5	310	/	

	5.0	330	330	Similar, and meet requirements of ISO5361:2016.
	5.5	330	330	
	6.0	360	360	
	6.5	360	360	
	7.0	380	380	
	7.5	380	380	
	8.0	390	390	
	8.5	390	390	
	9.0	400	400	
	9.5	400	400	
	10.0	400	400	
	I.D	Nasal uncuffed, ±5mm	Nasal uncuffed, ±3mm	/
	2.0	/	140	/
	2.5	/	145	/
	3.0	190	165	Similar, and meet requirements of ISO5361:2016.
	3.5	215	185	
	4.0	215	210	
	4.5	240	225	
	5.0	265	245	
	5.5	275	275	
	6.0	285	285	
	6.5	305	295	
	7.0	310	310	
	7.5	315	315	
	8.0	330	330	
	8.5	330	330	
	9.0	330	330	
	9.5	330	330	
	10.0	330	330	
	I.D	Oral cuffed, ±5mm	Oral cuffed, ±3mm	/
	2.0	/	/	/
	2.5	/	/	/
	3.0	170	/	Meet requirements of ISO5361:2016.
	3.5	180	/	
	4.0	190	/	
	4.5	215	/	
	5.0	225	230	Similar, and meet requirements
	5.5	240	245	
	6.0	255	255	

	6.5	265	265	of ISO5361:2016.
	7.0	290	295	
	7.5	310	300	
	8.0	325	310	
	8.5	335	320	
	9.0	350	335	
	9.5	350	350	
	10.0	350	350	
	I.D	Oral uncuffed, ±5mm	Oral uncuffed, ±3mm	/
	2.0	/	125	/
	2.5	/	135	/
	3.0	170	155	Similar, and meet requirements of ISO5361:2016.
	3.5	180	175	
	4.0	190	200	
	4.5	215	215	
	5.0	225	230	
	5.5	240	245	
	6.0	255	255	
	6.5	265	265	
	7.0	290	295	
	7.5	310	300	
	8.0	325	310	
	8.5	335	320	
	9.0	350	335	
	9.5	350	350	
	10.0	350	350	
Material		PVC	PVC	Same
Performance		Conforms to ISO5361	Conforms to ISO5361	Same
Biocompatibility		Conforms to ISO10993-1	Conforms to ISO10993-1	Same
Labeling		Meet the requirements of 21 CFR Part 801	Meet the requirements of 21 CFR Part 801	Same
Sterility		Sterile, SAL: $1X10^{-6}$ ETO Sterilization	Sterile, SAL: $1X10^{-6}$ ETO Sterilization	Same
Single use		Yes	Yes	Same

Discussion of Similarities and Differences

As indicated by above comparison table our Yikang Endotracheal Tube has same intended use, and similar design, material, technical characteristics, principle of operation and performance as predicate device, Well Lead Endotracheal Tube under k042683.

The additional size endotracheal tubes (oral/nasal cuffed (I.D2.0-4.5), nasal cuffed(I.D 3.0-4.5), and oral cuffed (I.D 3.0-4.5)) of propose device when compared to predicate device all complied with the requirements specified by ISO5361: 2016, compliance testing indicated in section 18: performance testing of this submission. The tube length of the proposed device for every type and size was similar as the predicate device, and it met the tube length requirements specified by ISO5361: 2016. Therefore, the differences between our proposed device and legally market predicate device (additional size and tube length) did not raise different questions of safety or effectiveness.

Based on the comparison of intended use, design, material, operation principle, and performance, our YiKang Endotracheal Tube is substantial equivalent to its predicate device which approved by FDA under K042683.

Summary of Performance testing

Performance testing have been conducted on YiKang Endotracheal Tube per ISO5361: 2016, and all the testing results meet requirements of ISO5361: 2016 and defined acceptance criteria. Detailed testing conducted as follows:

- Cuff diameter
- Cuff herniation
- Cuff leakage
- Tube collapse
- Kink resistance
- Tracheal seal

Biocompatibility

The YiKang Endotracheal Tube passed biocompatibility testing of cytotoxicity, sensitization, irritation, acute systemic toxicity, material–mediated pyrogenicity, subchronic toxicity, genotoxicity, and implantation per ISO10993-1.

Conclusion

Based on the information included in this premarket notification submission, and in accordance with 21 CFR Part 807 (E), Jiangxi Yikang Medical Instrument Group Co., LTD. concludes that the YiKang Endotracheal Tube is substantially equivalent to the predicate device cleared under K042683 without raising different questions of safety and effectiveness.