May 6, 2021

Haolang Medical USA Corporation
% Field Fu
Senior Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Bloack A, Zhongguan Times Square,
Xili Town
Shenzhen, Guangdong 518000
China

Re: K201697
Trade/Device Name: Umbilical Vessels Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOS
Dated: March 29, 2021
Received: April 5, 2021

Dear Field Fu:

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,

Payal Patel
Acting Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K201697

Device Name
UMBILICAL VESSELS CATHETER

Indications for Use *(Describe)*

UMBILICAL VESSELS CATHETER is intended for short-term vascular access via umbilical vessels in neonatal patients:
Via the umbilical artery:
---sampling of blood,
---measurement of intravascular arterial pressure.
Via the umbilical vein:
---infusion (simultaneous infusion of several medicinal products for the dual lumen catheter).

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

1. Contact Details

1.1 Applicant information

Applicant Name	Haolang Medical USA Corporation.
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Contact person's e-mail	lisa.xu@haolangmed.com
Date Prepared	May 30, 2020

1.2 Submission Correspondent

卓远天成	Shenzhen Joyantech Consulting Co., Ltd 1713A, 17th Floor, Block A, Zhongguan Times Square, Liuxian Avenue, Xili Town, Nanshan District, Shenzhen, Guangdong Province, China
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Website	http://www.cefda.com

2. Device information

Trade name	Umbilical Vessels Catheter
Common name	Umbilical Vessels Catheter
Model	Single lumen catheter, dual lumen catheter
Classification	Ⅱ
Classification name	Intravascular Catheter
Product code	FOS
Regulation No.	880.5200

3. Legally Marketed Predicate Device

Trade Name	Umbilical Vessels Catheter
510(k) Number	K130725
Product Code	FOS
Manufacturer	Covidien

4. Device Description

The UMBILICAL VESSELS CATHETER has catheters in single lumen and dual lumen. The catheters tube is made of radiopaque polyurethane which is insert molded to a polyurethane hub. The insertion tip of the catheter has been heat melted to form a smooth, rounded tip to reduce tissue trauma upon insertion.

Placement of the device is facilitated by depth markings, which are printed on the catheter at 1 cm intervals, beginning at 5 cm from the insertion tip and continuing to 40 cm from the tip. Catheter placement must be confirmed by x-ray.

The UMBILICAL VESSELS CATHETER has 17 primary configurations: Catheters in 2 Fr., 2.5 Fr., 2.8 Fr., 3 Fr., 3.5 Fr., 4 Fr., 5 Fr., 6 Fr., 6.5 Fr. and 7 Fr. for Single lumen; 2.8 Fr., 3 Fr., 3.5 Fr., 4 Fr., 5 Fr., 6 Fr. and 6.5 Fr. for dual lumen. Each device will continue to be packaged in a Tyvek pouch; 20 pouches are packaged in a carton. The UMBILICAL VESSELS CATHETER does not contain DEHP and is Ethylene Oxide sterilized. The product and packaging are not made of natural rubber latex.

5. Intended Use/Indication for Use

UMBILICAL VESSELS CATHETER is intended for short-term vascular access via umbilical vessels in neonatal patients:

Via the umbilical artery:

---sampling of blood,

---measurement of intravascular arterial pressure.

Via the umbilical vein:

---infusion (simultaneous infusion of several medicinal products for the dual lumen catheter).

6. Substantial Equivalence Comparison for Umbilical Vessels Catheter

Item	**Proposed Device:** Umbilical Vessels Catheter	**Predicate Device:** Umbilical Vessels Catheter **(K**130725**)**	**Comments**
Product Code	FOS	FOS	Same
Intended Use/Indication for use	UMBILICAL VESSELS CATHETER is intended for short-term vascular access via umbilical vessels in neonatal patients: Via the umbilical artery: ---sampling of blood, ---measurement of intravascular arterial pressure. Via the umbilical vein: ---infusion (simultaneous infusion of several medicinal products for the dual lumen catheter).	The Argyle TM Polyurethane Umbilical Vessel Catheter is intended for short-term vascular access via umbilical vessels in neonatal patients.	SE, only wording is different (01).
Catheter Type	Single lumen and dual lumen	Single lumen	Different (02)
Catheter size	**Single lumen:** (2 Fr, 2.5Fr, 2.8Fr, 3.0Fr, 3.5Fr, 4.0Fr, 5.0Fr, 6.0Fr, 6.5Fr, 7.0Fr) x (15cm, 20cm, 25cm, 28cm, 30cm, 32cm, 34cm, 35cm, 40cm); **Dual lumen:** (2.8Fr, 3.0Fr, 3.5Fr, 4.0Fr, 5.0Fr, 6.0Fr, 6.5Fr) x (15cm, 20cm, 25cm, 28cm, 30cm, 32cm, 34cm, 35cm, 40cm).	2.5 Fr x 25 cm, 3.5 Fr x 25 cm, and 5 Fr x 25 cm	Different (03)
Operation mode	Manual	Manual	Same
Radio-detectability	Yes	Yes	Same

Item	**Proposed Device:** Umbilical Vessels Catheter	**Predicate Device:** Umbilical Vessels Catheter **(K**130725**)**	**Comments**
water flow rate	The flowrate for each lumen is not less than 80% of the Nominal value for catheters of nominal outside diameter less than 1.0; and the flowrate for each lumen is not less than 90% of the Nominal value for catheters of nominal outside diameter equal to 1.0 or greater.	Not publicly available	Comply with ISO 10555-1
Peak tensile force	More than 5N, 10N, or15N	Not publicly available	SE (Comply with ISO 10555-1)
Freedom from leakage	No leakage for liquid and air	Not publicly available	SE (Comply with ISO 10555-1)
Material	Polyurethane	Not publicly available	SE (Comply with ISO 10993 series)
	POM M270-44	Not publicly available	

Discussion on differences from the predicate device:

01:

The Umbilical Vessels catheter indications for use is more specific than the predicate. The indications for use for other currently marketed Umbilical catheters on the market are similar as they are indicated for blood sampling, pressure monitoring and administration of fluids and medications. Although the subject device and the predicate device wording is different, the intended use is the same.

02 & 03:

The subject device is available in single and double lumen catheter configuration, with sizes 2Fr to 7Fr and 15-40 cm lengths. The predicate device is only available in a single lumen configuration 2.5 Fr to 5 Fr 25 cm length. The Umbilical catheters currently on the market come in both single and double lumen configurations and are available in various sizes lengths between 2 Fr to 8 Fr.

Performance testing was performed per recognized standards ISO 10555-1 and ISO 594-1/ISO 594-2, demonstrating that differences in physical characteristics (e.g. single lumen or dual lumen, length, size, etc.) do not raise new or different questions of safety and effectiveness.

7. Non-clinical Testing

All nonclinical testing performed on new devices is to demonstrate the substantial equivalence to the predicate devices. Tests setup and execution are performed in accordance with applicable standards. Results of the tests demonstrate the compliance to the standards.

a) The tests concerned sterilization and shelf life as follow:

Standard	Standard Title	Test Results
ISO 11135:2014	Sterilization of health-care products - Ethylene oxide -Requirements for the development, validation and routine control of a sterilization process for medical devices	Pass
ASTM F88/F88M-09	Standard Test Method for Seal Strength of Flexible Barrier Materials	Pass
ASTM F1886-98	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection	Pass
ASTM F1929-98 (Reapproved 2004)	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	Pass
ASTM F1140-00	Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages for Medical Applications	Pass
ASTMD4169-05	Standard Practice for Performance Testing of Shipping Containers and Systems	Pass
ASTM D3078-02	Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission	Pass
ASTM F 1886-98	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection	Pass

b) The tests concerned biocompatibility as follow:

Test Item	Reference	Standard Title	Test Results
Genotoxicity	ISO 10993-3:2014	Biological evaluation of medical devices —Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	Pass
Hemocompatibility, Hemolytic	ISO 10993-4:2006; ASTM F756，	Biological evaluation of medical devices —Part 4: Selection of tests for interactions with blood;	Pass

		Standard Practice for Assessment of Hemolytic Properties of Materials.	
Cytotoxicity	ISO 10993-5:2009	Biological evaluation of medical devices —Part 5: Tests for in vitro cytotoxicity	Pass
Implantation	ISO 10993-6:2016	Biological evaluation of medical devices —Part 6: Tests for local effects after implantation	Pass
EO,ECH residual	ISO 10993-7:2008	Biological evaluation of medical devices —Part 7: Ethylene oxide sterilization residuals	Pass
Sensitization	ISO10993-10:2010	Biological evaluation of medical devices —Part 10: Tests for irritation and skin sensitization	Pass
Irritation or Intracutaneous reactivity	ISO 10993-10:2010	Biological evaluation of medical devices —Part 10: Tests for irritation and skin sensitization	Pass
Acute Systemic toxicity	ISO 10993-11:2006	Biological evaluation of medical devices —Part 11: Tests for systemic toxicity	Pass
Subacute Subchronic toxicity	ISO 10993-11:2006	Biological evaluation of medical devices —Part 11: Tests for systemic toxicity	Pass
Material-Mediated Pyrogenicity	ISO 10993-11:2006	Biological evaluation of medical devices —Part 11: Tests for systemic toxicity	Pass
Limulus Amebocyte Lysate	USP<85>	United States Pharmacopoeia	Pass

c) Software validation

Not applicable, the subject devices are non-active products.

d) Electric safety

Not applicable, the subject devices are non-active products.

e) The tests concerned performance-bench as follow:

Standard	Standard Title	Test Result
ISO 10555-1:2013	Intravascular catheters — Sterile and single-use catheters —Part 1: General requirements	Pass
ISO 594-1:1986	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements	Pass

Standard	Standard Title	Test Result
ISO 594-2:1998	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings	Pass
ISO7886-1:2017	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use	Pass

8. Animal study data

Substantial equivalence does not depend on animal study data.

9. Clinical Testing

Substantial equivalence does not depend on the clinical test data.

10. Conclusions

Based on device comparison information and non-clinical bench testing, the proposed device is substantially equivalent to legally marketed predicate devices (K130725).