August 17, 2023

Anhui Tiankang Medical Technology Co., Ltd.
Zhang Yong
Management
No. 228, Weiyi Road, Economic Development Zone
Tianchang, Anhui 239300
China

Re: K222773
Trade/Device Name: Feeding Tube
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube And Accessories
Regulatory Class: Class II
Product Code: PIF
Dated: December 5, 2022
Received: December 6, 2022

Dear Zhang Yong:

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,

Sivakami Venkatachalam -S

for
Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222773

Device Name
Feeding Tube

Indications for Use *(Describe)*
This product is intended for use in neonatal and pediatric patients to provide nutrition via nasal or orogastric placement. The Polyurethane Feeding Tube is not intended for use beyond 30 days. The PVC Feeding Tube is not intended for use beyond 24h

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

I Submitter

Device submitter: Anhui Tiankang Medical Technology Co., Ltd.
No.228, Weiyi Road, Economic Development Zone, Tianchang City, Anhui, China.

Contact person:
Name: Zhang yong
Title: Management representative
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II Device

Trade Name of Device: Feeding Tube
Common Name: Gastrointestinal tubes with enteral specific connectors
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: Class II
Product code: PIF
Review Panel: Gastroenterology/Urology

III Predicate Device 1

Trade name:	Pediatric Nasogastric Feeding Tubes - Single ENFit Port
Regulation name:	Gastrointestinal tube and accessories
Classification:	Class II
Product Code:	PIF
Premarket Notification:	K210598
Manufacturer:	Cair Lgl

IV Device description

The Feeding Tube consists of the following main components: a feeding tube single lumen catheter and an enteral only connector hub with integral tethered connection closure plug. The catheter tubing is made of Polyurethane or PVC. The catheter tubing has an orange or purple radiopaque stripe of barium sulfate embedded in the tubing wall which can be visualized on x-ray, for exact placement of the tip. The single lumen catheter tubing has side holes for better flow and to provide multiple openings for aspiration.
The proposed Feeding Tube is sterilized by Ethylene Oxide Gas to achieve a SAL of 10-6 and supplied sterility maintenance package which could maintain the sterility of the device during the shelf life of three years.

V Indications for use

This product is intended for use in neonatal and pediatric patients to provide nutrition via nasal or orogastric placement.The Polyurethane Feeding Tube is not intended for use beyond 30 days. The PVC Feeding Tube is not intended for use beyond 24 hours.

VI Comparison of technological characteristics with the predicate devices

The Feeding Tube are substantially equivalent to the currently marketed predicate Pediatric Nasogastric Feeding Tubes - Single ENFit Port. Table 6-1 is a detailed comparison of the Feeding Tube to the predicate devices regarding substantial equivalence.

Table 6-1 Substantial equivalence discussion for Feeding Tube

Device feature	Subject Device	Predicate Device K210598	Comment
Product	Feeding Tube	Pediatric Nasogastric Feeding Tubes - Single ENFit Port	/
Product code	PIF	PIF	Same
Regulation Number	21CFR 876.5980	21CFR 876.5980	Same
Indications for use	This product is intended for use in neonatal and pediatric patients to provide nutrition via nasal or orogastric placement.The Polyurethane Feeding Tube is not intended for use beyond 30 days. The PVC Feeding Tube is not intended for use beyond 24 hours.	The Pediatric Nasogastric Feeding Tubes - Single ENFit Port are intended for enteral feeding to deliver nutrition, fluids, and medications to the patient from an enteral feeding syringe or feeding set designed with ENFit connectors for enteral applications. This product is single use for no longer than 29 days.	Difference Comment 1
Environment of Use	Unspecified –Prescription Only	Unspecified –Prescription Only	Same
Intended Users	Trained personnel well versed in anatomical landmarks, safe technique, and potential complications must perform the procedure.	Physicians, nurses, and trained clinicians (by facility policy)	Same
Patient Population	Neonatal and Pediatric patients	Neonatal and Pediatric patients	Same
Single Use	Single Use	Single Use	Same

Device feature	Subject Device	Predicate Device K210598	Comment
Connector	Compliant with ISO 80369-3	Compliant with ISO 80369-3	Same
Radiopacity Verification	Compliant with ISO 20695:2020	Compliant with ISO 20695:2020	Same
Tube Markings	Compliant with ISO 20695:2020	Compliant with ISO 20695:2020	Same
French Sizes	4,5,6.5,8,10,12	4, 5, 6, 8, 10, 12	Difference Comment 2
Lengths	40cm, 60cm, 90cm, 105cm, 109cm	40cm, 60cm, 90cm	Difference Comment 3
Liquid Leakage Testing	Feeding tube set shall not show signs of leakage sufficient to form a falling drop of water while being subjected to the internally applied pressure of 50 kPa to 60 kPa.	Tested and met updated standard ISO 20695:2020 Enteral Feeding Systems – Design and Testing	Same
Component and Material	Head Melted Tube: TPU/PVC Hub: TPU/ABS Tethered Bolt: PVC	Tube: Polyurethane Cap: Polypropylene Connector: ABS Tether: thermoplastic polyurethane	Difference Comment 4
Tensile Testing	Tested and met updated standard ISO 20695:2020 Enteral Feeding Systems – Design and Testing	Tested and met updated standard ISO 20695:2020 Enteral Feeding Systems – Design and Testing	Same
Fluid Leakage: Connector	The connector shall not leak applied pressure of between 300 kPa and 330 kPa per ISO 80369-3 and ISO 80369-20.	Tested per ISO 80369-20 and met the standards of 80369-3 for fluid leakage.	Same
Stress Cracking: Connector	The connector shall have adequate resistance to stress cracking per ISO 80369-3 a80369-20.	Tested per ISO 80369-20 and met the standards of ISO 80369-3 for stress cracking.	Same
Resistance to separation from axial load: connector	The connector shall not separate from the reference connector applied axial force per ISO 80369-3 and ISO 80369-20.	Tested per ISO 80369- 20 and met the standards of ISO 80369-3 for resistance to separation from axial load.	Same

Device feature	Subject Device	Predicate Device K210598	Comment
Resistance to separation from unscrewing: connector	The connector shall separate from the reference connector applied unscrewing torque less than 0.26 N.m per ISO 80369-3 and ISO 80369-20.	Tested per ISO 80369-20 and met the standards of ISO 80369-3 for separation from unscrewing.	Same
Resistance to overriding: connector	The connector shall not override the threads or lugs of the reference connector applied torque of between 0.15 N.m to 0.17 N.m per ISO 80369-3 and ISO 80369-20.	Tested per ISO 80369-20 and met the standards of ISO 80369-3 for resistance to overriding.	Same
Connector	The connector shall be compatible with ISO 80369-3 reference connectors.	Evaluated per ISO 80369-3 for ENFit dimensional verification	Same
	Non- ENFit Connector	None	Difference Comment 5
Biocompatibility	Compliant with Use of International Standard ISO 10993-1, " Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"	Compliant with Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"	Same
Sterility Condition	Sterile	Sterile	Same
Sterile Method	EO Sterilized	EO Sterilized	Same

Difference comment 1

The difference between subject device and predicate device is only in textual expressions, and the actual indications for use are not different, which will not affect the safety and performance of the device.

Difference comment 2

The french sizes of predicate device are covered by subject device, so this difference will not affect the safety and performance of the device

Difference comment 3

The lengths of 105cm and 109cm of the predicate device are not covered by the predicate device. The operator will select the corresponding length of the device according to the clinical needs. At the same time, the device has passed the performance test, so the difference will not affect the safety and performance of the device.

Difference comment 4
subject device is different from predicate device in material, the biocompatibility test has been performed on subject device according to ISO 10993, the result does not show any adverse effect which can demonstrate the safety of proposed device. Therefore, this difference does not raise new safety and effectiveness issues for the device.

Difference Comment 5
The predicate device does not contain a Non-ENFit Connector, and since the subject device has been tested by the connector and the results show that it does not present the risks contemplated by ISO 80369-1, this does not affect the safety and effectiveness of the product device

VII Performance data
The following performance data were provided in support of the substantial equivalence determination.
Biocompatibility testing
Biocompatibility of the Feeding Tube was evaluated in accordance with ISO 10993-1:2018 for the body contact category of “Surface medical device–mucosal membrane” with a contact duration of “prolonged (＞24h to 30d)”. The following tests were performed, as recommended：

In Vitro Cytotoxicity Test	ISO 10993-5: 2009
Intracutaneous Reactivity Test	ISO 10993-10: 2010
Skin Sensitization Test	ISO 10993-10: 2010
Acute systemic toxicity	ISO 10993-11:2017
Subacute toxicity	ISO 10993-11:2017
Implantation effects	ISO 10993-6:2017

Sterilization and shelf life testing
The sterilization method has been validated to ISO11135, which has thereby determined the routine control and monitoring parameters.
The testing is performed according to the following standards:

EO residue	ISO 10993-7:2008
ECH residue	ISO 10993-7:2008

The shelf life of three years is determined based on stability studies which include ageing test according to FDA recognized standard ASTM F1980-16.
Package integrity testing was conducted on the final, packaged, and sterile devices after

environmental conditioning and simulated transportation. All packaging deemed acceptable for protection of product and sterility maintenance.

The testing is performed according to the following standards:

Seal strength	ASTM F88/F88M-15
Blue Dye Penetration	ASTM F 1929-2015
Seal Integrity (Visual Inspection)	ASTM F 1886/ F 1886M-16

Performance testing

Performance testing is performed according to the following standards:

- ISO 80369-3:2016: Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications
- ISO 80369-20:2015: Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods
- ISO 20695 Enteral feeding systems - Design and testing

XI Clinical Test Conclusion

No clinical study is included in this submission.

X Conclusion

The Feeding Tube is substantially equivalent to its predicate device. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device.