April 9, 2021

Medcaptain Life Science Co., Ltd.
Mr. David Xia
601, Building C, Jinweiyuan Industrial Park,
Pingshan District
Shenzhen, Guangdong 518118
CHINA

Re: K202748
Trade/Device Name: Enteral Feeding Catheter
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube and accessories
Regulatory Class: Class II
Product Code: KNT
Dated: February 2, 2021
Received: February 8, 2021

Dear David Xia:

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,

Yasaman Z. Ardeshirpour -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202748

Device Name
Enteral Feeding Catheter

Indications for Use *(Describe)*
Enteral feeding catheter is intended for use in those patients who require intermittent or continuous tube feedings via the nasogastric or nasoenteric route. The target population is adults and pediatrics.

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

I. Submitter/510(k) Holder

Submission:	Traditional 510(k) Premarket Notification
Submitter:	MEDCAPTAIN LIFE SCIENCE CO., LTD.
Address:	601, Building C, Jinweiyuan Industrial Park, Pingshan District, Shenzhen, Guangdong, CN 518118.
Contact Person:	David Xia
Telephone:	+86-755-28380626
Telefax:	+86-755-84517910
Email:	david.xia@medcaptain.com
Date prepared:	April 9, 2021

II. Device

Device Trade Name:	Enteral Feeding Catheter
Device Common Name:	Feeding Tube or NG/NI Tube
Regulatory Name:	Gastrointestinal Tube and Accessories
Regulation Number:	21 CFR 876.5980
Product Code:	KNT
Product Code Name:	Tubes, Gastrointestinal (And Accessories)
Regulatory Class:	Class II
Device Panel:	Gastroenterology and Urology

III. Predicate Device and reference device

The Enteral Feeding Catheter is substantially equivalent to the following device: Corpark Enteric Feeding Tube W/Guide Tip (K821906, CORPARK MEDSYSTEMS) cleared on December 29, 2008.

510(k) submitter/holder:	CORPAK MEDSYSTEMS
510(k) number:	K821906
Device Trade Name:	Corpark Enteric Feeding Tube W/Guide Tip
Regulatory Name:	Gastrointestinal Tube and Accessories
Regulation Number:	21 CFR 876.5980
Product Code:	KNT
Product Code Name:	Tubes, Gastrointestinal (And Accessories)
Regulatory Class:	Class II
Device Panel:	Gastroenterology and Urology

The reference device, Cediflo Enteral Feeding Tubes & Cediflo Junior Enteral Feeding Tubes (K181787, Cedic S.R.L.) was used in this submission.

510(k) submitter/holder:	Cedic S.R.L.
510(k) number:	K181787
Device Trade Name:	Cediflo Enteral Feeding Tubes & Cediflo Junior Enteral Feeding Tubes
Regulatory Name:	Gastrointestinal Tubes With Enteral Specific Connectors
Regulation Number:	21 CFR 876.5980
Product Code:	PIF
Product Code Name:	Gastrointestinal Tubes With Enteral Specific Connectors
Regulatory Class:	Class II
Device Panel:	Gastroenterology and Urology

IV. Device Description

The Enteral Feeding Catheter is composed of a feeding catheter and stylet and can be divided into Funnel type and Enfit type as per the structure of the feeding catheter. For Funnel type, the feeding catheter is composed of tip, body, Y connector. The Y connector has integrated protective cap and strap. For Enfit type, the feeding catheter is composed of tip, body, Y connector, protective cap, and strap. The feeding catheter is made of polyurethane tube with BNF-II-79 hydrophilic coating. The feeding catheter is available in sizes of 6Fr, 8Fr, 10Fr and 12Fr and lengths of 70cm, 100cm, 120cm and 140cm. The length is measured from the distal tip to the proximal hub. The distal end of the feeding catheter features a sideport and is a smooth rounded finish. The proximal end of the feeding catheter features a funnel Y connector that is made of polyurethane or Enfit Y connector that is made of polycarbonate. A stainless-steel stylet with a length corresponding to the feeding catheter is fit inside the feeding catheter.

The subject device, Enteral Feeding Catheter, may be introduced directly when there is adequate peristalsis and no gastric outlet obstruction. Alternatively, the feeding catheter may be passed over a stylet. The feeding catheter is intended to be indwelling up to four weeks and is for single-use only.

The Enteral Feeding Catheter has model numbers of EF4064M, EF4084M, EF4084H, EF4104M, EF4104L, EF4124L, EF4124X, EF4065M, EF4085M, EF4085H, EF4105M, EF4105L, EF4125L and EF4125X. The differences of each model are listed in the following table 1.

Table 1 Models of Enteral feeding catheter

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Enteral feeding catheter					
Models	Feeding catheter			Stylet	
	Type	Size	Effective length(cm)	Effective length(cm)	Color of hub
EF4064M	Funnel	6Fr	70	70	Green
EF4084M	Funnel	8Fr	70	70	Blue
EF4084H	Funnel	8Fr	100	100	Blue
EF4104M	Funnel	10Fr	70	70	Black
EF4104L	Funnel	10Fr	120	120	Black
EF4124L	Funnel	12Fr	120	120	White
EF4124X	Funnel	12Fr	140	140	White
EF4065M	Enfit	6Fr	70	70	Green
EF4085M	Enfit	8Fr	70	70	Blue
EF4085H	Enfit	8Fr	100	100	Blue
EF4105M	Enfit	10Fr	70	70	Black
EF4105L	Enfit	10Fr	120	120	Black
EF4125L	Enfit	12Fr	120	120	White
EF4125X	Enfit	12Fr	140	140	White

V. Indications for Use

Enteral Feeding Catheter is intended for use in those patients who require intermittent or continuous tube feedings via the nasogastric or nasoenteric route. The target population is adults and pediatrics.

VI. Comparison of Technological Characteristics with the Predicate Device

The subject device, Enteral Feeding Catheter, and the predicate device, Corpark Enteric Feeding Tube W/Guide Tip, are substantially equivalent in that these devices have similar intended use, technological characteristics, target user, patient population, placement location, use environment, etc. The subject device and predicate device similarly establish an enteral delivery for feeding. The subject device and predicate device have identical characteristics including the number of side port on the distal end of the catheter and rounded distal tip, tube material and tube type. The subject device and predicate device are inserted into stomach, duodenum or jejunum of the patient via the nasogastric or nasoenteric route.

The differences between the subject and the predicate device include the materials of coating, tube size and length, sterilization, energy type and shelf life. The materials

of subject device are biocompatible based on biocompatibility tests. The tube size and length of the subject device is covered by those of the predicate device. Sterilization process has been proved to be qualified and can keep SAL=10^{-6}. The sterility and energy type of the subject device is addressed from a technological perspective by the reference device, Cediflo Enteral Feeding Tubes. The shelf life has been proved that the technical performance of the device will be qualified within 3 years. All these differences do not raise any new issues of safety and/or effectiveness.

VII. Performance Data

The subject device, Enteral Feeding Catheter, was subjected to the following applicable testing to assure reliable design and performance under the specified testing parameters:

Biocompatibility Testing:

Per ISO 10993-1: 2018 and FDA guidance, the following tests were performed to ensure the biocompatibility of the subject device.

- In vitro cytotoxicity, per ISO 10993-5: 2009
- Implantation, per ISO 10993-6: 2016
- Intracutaneous reactivity, per ISO 10993-10: 2010
- Skin sensitization, per ISO 10993-10: 2010
- Acute systemic toxicity, per ISO 10993-11: 2017
- Subacute toxicity, per ISO 10993-11: 2017
- Pyrogenicity, per ISO 10993-11: 2017 and USP General Chapter <151>

Bench Testing (Zero Time and Accelerated Aged):

Per EN 1615: 2000, EN 1618: 1997, ISO 80369-3: 2016, etc., the following tests were performed to ensure performance/functionality of the subject device.

- Appearance, per similar device and product characteristics.
- Dimensions, per similar device and product characteristics.
- Tensile property, per EN 1615: 2000.
- Connector compatibility, per EN 1615: 2000.
- Connector tensile property, per EN 1615: 2000.
- Liquid leakage, per EN 1615: 2000.
- Flow rate, per EN 1618: 1997.
- Acid assistance, per product characteristics.
- Coating lubricity, per product characteristics.
- Radio-detectability, per similar device and product characteristics.
- Stylet tensile force, per EN 1618: 1997.
- Style corrosion, per ISO 11070: 2014.
- Style fracture test, per ISO 11070: 2014.

- Chemical performance, per ISO 8536-4: 2019.
- Sterility, per EN 1615: 2000 and ISO 11135: 2014.
- Bacterial endotoxin, per ANSI/AAMI ST72: 2011.
- Package performance, per ISO 11607-1: 2019 and ISO 11607-2: 2019.
- Shelf Life Validation, per ASTM F1980-16.

Clinical Tests:

Clinical tests were not required to demonstrate performance of Enteral feeding catheter. Product functionality has been adequately assessed by non-clinical tests.

Animal Tests:

Animal tests were not required to demonstrate performance of Enteral feeding catheter. Product functionality has been adequately assessed by non-animal tests.

VIII. Conclusions

The results of these tests confirm that the Enteral Feeding Catheter meets the design input requirements based on the intended use and support the conclusion that this device does not raise new questions of safety and/or effectiveness and is substantially equivalent to the predicate device, Corpark Enteric Feeding Tube W/Guide Tip (K821906, CORPARK MEDSYSTEMS).