April 25, 2019

Cedic S.r.l.
% Crystal Koelper
President
Koelper Consulting LLC
268 Baltimore Drive
North Barrington, IL 60010

Re: K181787
Trade/Device Name: Cediflo Enteral Feeding Tubes & Cediflo Junior Enteral Feeding Tubes
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: PIF
Dated: March 12, 2019
Received: March 14, 2019

Dear Crystal Koelper:

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,

Mark J. Antonino -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*
K181787

Device Name
Cediflo Enteral Feeding Tubes & Cediflo Junior Enteral Feeding Tubes

Indications for Use *(Describe)*
The Cediflo Enteral Feeding Tubes are intended for the administration of enteral nutrition, fluids, and/or medications by the nasoenteric route into the stomach or small intestine. Indicated for patients 2 years and above which require nutritional support, are not able to meet their nutritional requirements by oral intake and have functioning and accessible gastrointestinal tract.Maximum duration of use: 42 days.

The Cediflo Junior Enteral Feeding Tubes are intended for the administration of enteral nutrition, fluids, and/or medications by the nasoenteric route into the stomach or small intestine. Indicated for neonatal and pediatric patients which require nutritional support, are not able to meet their nutritional requirements by oral intake and have functioning and accessible gastrointestinal tract.

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.

Section 5: 510(k) Summary of Safety and Effectiveness

Submitter / 510(k) Holder

Company:	Cedic s.r.l.
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Phone:	+1-847-345-6920
Contact Person:	Crystal Koelper
Date Prepared:	April 12, 2019

Device Name and Classification

Trade Name:	Cediflo Enteral Feeding Tubes & Cediflo Junior Enteral Feeding Tubes
Model Number(s):	N###
Classification Name:	Gastrointestinal Tube and Accessories (21 CFR 876.5980)
Product Code:	PIF
Class:	II

Predicate Device(s)

1) Degania Aquarius Nasal Feeding Tubes (K141753)
2) Corpak MedSystems Neonatal Nasogastric Feeding Tube (K831328)

Device Description

The Cediflo and Cediflo Junior Enteral Feeding Tubes are sterile, single use devices intended for use in acute care facilities, long-term care facilities, and home. They are made from radiopaque polyurethane tubing printed with centimeter markings and bonded at the proximal end to a rigid male ENFit connector with a tethered cap. The proposed device is offered in lengths of 50 cm to 120 cm and diameters of 5 Fr (1.66 mm) to 16 Fr (5.33 mm). These tubes are supplied with or without a guidewire. The distal tip of the polyurethane tubing is closed and rounded with four side holes to allow for fluid flow.

The male ENFit connector of the proposed device is designed to comply with ISO 80369-3:2016 and allows for connection to enteral feeding specific sets and syringes while reducing the likelihood of misconnections to devices that are not intended for enteral administration. A twist on cap is tethered to the male ENFit connect via a strap.

The guidewire, when provided, of the proposed device is a stainless-steel braided wire with a rounded distal tip which is pre-loaded into the polyurethane feeding tube. The guidewire stiffens the polyurethane tubing to aide in insertion of the device. The guidewire has a lubricious coating that aids in removal of the guidewire from the feeding tube in situ. A flow through guidewire connector is attached to the proximal end of the guidewire which provides the connection between the wire and feeding tube.

Criteria for Comparison	Proposed Device Compared to Predicate #1 Aquarias Nasal Feeding Tubes	Proposed Device Compared to Predicate #2 Corpak Medsystems Neonatal Nasogastric Feeding Tubes
Intended Use		
Indications	Similar and SE	Similar and SE
Clinical Settings	Same	Same
Target Population	Similar (predicate #1 is not intended for use in neonates)	Similar (predicate #2 is not intended for use in adults)
Design Characteristics		
Outer Diameter:	Similar and SE (Predicate devices have 5 Fr to 16 Fr diameters).	Similar and SE (Predicate devices have 5 Fr to 8 Fr diameters)
Length	Similar and SE, (Predicate devices are 50 cm to 120 cm in length.)	Similar and SE (Predicate devices are 22” to 36” in length.)
Sterility	Different but SE (Sterility of predicate device #1 is unknown)	Similar and SE (Predicate devices are supplied sterile or non-sterile)
Access Port	Same	Different (Predicate has flexible Y port funnel)
Caps	Same	Different (Predicate device has tethered, male friction fit plugs)
Tubing	Same	Same
Distal Tip	Similar and SE (Predicate device distal tips are weighted and non-weighted with hydrophilic coating)	Similar and SE (Predicate devices distal tips are single opening, close ended, weighted or non-weighted with hydrophilic coating.)
Guidewire/Stylet	Similar and SE (Predicate devices provided with and without a guidewire/stylet.)	Similar and SE (Predicate devices provided with or without a 2 strand twisted wire.)
Materials		
Access Port	Different (Material is unknown)	Different (Flexible polyurethane)
Caps	Different (Material is unknown)	Different (Flexible polyurethane)
Tubing	Similar and SE	Similar and SE
Guidewire/Stylet	Different (Unknown)	Similar and SE
Performance		
Use/Human Factors	Same	Different – Predicate devices connect to legacy administration sets and syringes
Theory of operation	Same	Same
Risk assessment	Same	Same
Safety		

Mechanical	Same – both are designed and constructed in compliance with EN1615:2000 and ISO 80369-3:2016	Different –Predicate device design is not compliant with ISO 80369-3:2016
Electrical	Same - not electrical devices	Same - not electrical devices
Radiation	Same - not radiation emitting devices	Same - not radiation emitting devices

Indications for Use

The Cediflo Enteral Feeding Tubes are intended for the administration of enteral nutrition, fluids, and/or medications by the nasoenteric route into the stomach or small intestine. Indicated for patients 2 years and above which require nutritional support, are not able to meet their nutritional requirements by oral intake and have functioning and accessible gastrointestinal tract. Maximum duration of use: 42 days.

The Cediflo Junior Enteral Feeding Tubes are intended for the administration of enteral nutrition, fluids, and/or medications by the nasoenteric route into the stomach or small intestine. Indicated for neonatal and pediatric patients which require nutritional support, are not able to meet their nutritional requirements by oral intake and have functioning and accessible gastrointestinal tract.

Product Comparison Summary

The proposed and predicate enteral feeding devices are all intended for enteral administration of nutrients, fluids, and/or medications into the alimentary tract via the natural nasoenteric route for use in the same clinical settings. The combined populations of the predicate devices and the proposed device are intended for use in the same patient populations. The use and theory of operation of the proposed and predicate devices are the same regardless of the differences in size of tubes offered and design features. These differences do not alter the intended use of the devices or impact the safety and effectiveness of the devices. Material differences of the proposed device from the predicate device have been successfully evaluated for biocompatibility per ISO 10993-1. Refer to Table 1 below for a summary of the product comparison.

Non-Clinical Performance Testing

Non-clinical performance testing was conducted to demonstrate that the Cediflo Enteral Feeding Tubes are substantially equivalent to the predicate device and are safe and effective for their intended use. In addition, Cediflo Enteral Feeding Tubes that underwent accelerated aging conditioning were tested to substantiate the product shelf life.

The following tests were performed:

- Biocompatibility testing per ISO 10993-1
- ISO 80369-3:2016 Testing, including:
  - Fluid leakage,
  - Stress cracking,

  - Resistance to separation from axial load,
  - Resistance to separation from unscrewing,
  - Resistance to overriding,
  - Disconnection by unscrewing, and
  - Dimensional verification.
- EN 1615:2000 Testing, including:
  - Leakage
  - Tensile Strength
  - Flow Rate with water and commercially available enteral nutrition
- ISO 11070 Testing on included guidewire, including:
  - Tensile Strength,
  - Fracture Resistance,
  - Flexion Resistance.
- Tubing Kink Resistance Testing per EN 13868:2002

Clinical Performance Testing

Clinical performance testing was not required to demonstrate the performance of the Cediflo Enteral Feeding Tubes. The Cediflo Enteral Feeding Tube performance has been adequately demonstrated by the completion of non-clinical performance testing.

Animal Testing

Animal testing was not required to demonstrate the performance of the Cediflo Enteral Feeding Tubes. The Cediflo Enteral Feeding Tube performance has been adequately demonstrated by the completion of non-clinical performance testing.

Conclusion

The results of the non-clinical performance testing demonstrate that the Cediflo Enteral Feeding Tubes are as safe and effective as the predicate device. Therefore, the proposed devices are substantially equivalent to the predicate devices.