DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 4, 2017

Cedic S.r.l.
% Roger Gray
VP, Quality And Regulatory
Donawa Lifescience Consulting S.r.l.
Piazza Albania, 10
Rome, 00153
Italy

Re: K162254
Trade/Device Name: Cedic Enteral ENFit Transition Connectors
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: PIO
Dated: March 29, 2017
Received: April 5, 2017

Dear Roger Gray:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Benjamin R. Fisher -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162254

Device Name
Cedic Enteral ENFit Transition Connectors

Indications for Use *(Describe)*

The Cedic F 00126 ENFit to Reverse Luer Transition Connector is intended to connect an enteral female ENFit giving set to the "g" port of the AbbVie PEG-J enteral male Luer catheter.

The Cedic F 00128 Luer to ENFit Transition Connector is intended to connect the AbbVie Duopa Medication Cassette Reservoir delivery system to an enteral male ENFit 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

Device Name:	Cedic F 00126 ENFit to Reverse Luer Transition Connector, and Cedic F 00128 Luer to ENFit Transition Connector
Type of 510(k) submission:	Traditional
Date of Submission:	8 August 2016
Manufacturer:	Cedic S.r.l. Biomedical Division Via Liberazione, 63/9 20068 Peschiera Borromeo (MI) Italy
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Phone: **Fax:** **Email:**	+39 06 578 2665 +39 06 574 3786 rgray@donawa.com
FDA Product Code:	PIO
FDA Regulation Number:	876.5980
FDA Classification Name:	Enteral Specific Transition Connectors
Classification Panel:	Gastroenterology and Urology
Common Name:	Transition Connectors for Enteral Applications
FDA Classification:	Class II
FDA Identification:	Facilitates enteral specific connections between ENFit connectors and non 80369-1 compliant enteral connectors.

Device Description

The introduction of new connectors to devices and accessories for enteral feeding applications, in order to help avoid misconnections with devices intended for other clinical applications, has resulted in the short-term need to connectors that will allow devices with existing ('legacy') end connectors to be connected with newer devices having end connectors meeting the relevant requirements of the ISO 80369 series of standards.

Cedic Enteral ENFit Transition Connectors are designed to facilitate enteral specific connections between ISO 80369-3 compliant connectors and non ISO 80369-1 compliant legacy enteral connectors.

This submission describes the Cedic ENFit to Reverse Luer Transition Connector and the Cedic Luer to ENFit Transition Connector. These Cedic ENFit Transition Connectors are intended for prescription use only.

The two transition connectors introduced by means of this submission are intended only for use with specific products commercialized in the US by Abbvie Inc., North Chicago, IL 60064-1802, USA, these being the AbbVie PEG-J enteral male Luer catheter (cleared under K142816) and the AbbVie Duopa Medication Cassette Reservoir (details available in DMF 26089) respectively.

Indications for Use

The Cedic F 00126 ENFit to Reverse Luer Transition Connector is intended to connect an enteral female ENFit giving set to the "g" port of the AbbVie PEG-J enteral male Luer catheter.

The Cedic F 00128 Luer to ENFit Transition Connector is intended to connect the AbbVie Duopa Medication Cassette Reservoir delivery system to an enteral male ENFit catheter.

Principle of operation, mechanism of action, and interaction with the patient

The Cedic Enteral ENFit Transition Connectors operate by providing a means of interconnecting incompatible enteral feeding device end fittings together, so that patient connection can take place when 'new generation' end fittings in accordance with ISO 80369-3 need to be connected to previous 'legacy' designs of end fitting.

The Cedic Enteral ENFit Transition Connectors are not intended to come into contact with the patient, but accidental contact may occur. The Cedic Enteral ENFit Transition Connectors have a central fluid path through which fluids flow into the patient during use.

Cedic ENFit Transition Connectors are not intended for a specific patient population: they can be used for any patients who need to use the Abbvie products to which they will be connected..

Device Specification

The ENFit (PGLock) ends of the connectors are designed in compliance with FDA-recognized standard ISO 80369-3 "*Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications*", and tested in accordance with FDA-recognized standard ISO 80369-20 "*Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods*". The Luer ends of the connectors are designed in compliance with ISO 594-2.

Manufacture

The Cedic ENFit Transition Connectors are manufactured by injection molding from polypropylene.

Performance Data

In relation to performance data for enteral transition connectors, the subject transition connectors follow the guidance provided in FDA publication 'Safety Considerations to Mitigate the Risks of Misconnections with Small-bore Connectors Intended for Enteral Applications: Guidance for Industry and Food and Drug Administration Staff', February 11, 2015.

Bench tests have been carried out on samples of the Cedic Transition Connectors. The tests carried out include:

- Enteral connector misconnection assessment
- Human factors
- Fluid leakage
- Stress cracking
- Resistance to separation from axial load
- Resistance to separation from unscrewing
- Resistance to overriding
- Disconnection by unscrewing

Predicate device

The Predicate Device selected for comparison with the Cedic ENFit Transition Connectors is:

Predicate Device: ..... AMT Enteral Transition Adapters
Sponsor: ..... Applied Medical Technology, Inc.
510(k) Number: K150034
Clearance Date: ..... 9 June 2015
FDA Product Code: ..... PIO
Classification Name: ..... Enteral specific transition connectors
Regulation No: 876.5980

Substantial equivalence:

Table 1: Predicate device comparison table

Item	Predicate device	Subject device	Similarity
Device description	The AMT Enteral Transition Adapters come in 5 configurations: • Male Enfit to Male Luer Adapter • Female Enfit to Female Luer Adapter • Female Enfit to Y-Port (Bolus/Luer) Adapter • Female Enfit to Bolus Adapter • Male Enfit to Christmas-tree Adapter	The Cedic Enteral ENFit Transition Connectors come in 2 configurations: • Male ENFit to Female Luer Transition Connector with Cap • Male Luer to Female ENFit Transition Connector with Cap	Very similar

Table 1: Predicate device comparison table			
Item	**Predicate device**	**Subject device**	**Similarity**
Indications for Use	The AMT Enteral Transition Adapters are intended to facilitate enteral specific connections between AAMI/CN3(PS) compliant connectors and non ISO 80369-1 compliant legacy enteral connectors.	The Cedic F 00126 ENFit to Reverse Luer Transition Connector is intended to connect an enteral female ENFit giving set to the “g” port of the AbbVie PEG-J enteral male Luer catheter. The Cedic F 00128 Luer to ENFit Transition Connector is intended to connect the AbbVie Duopa Medication Cassette Reservoir delivery system to an enteral male ENFit catheter.	Substantially equivalent
Geometry of ENFit connecting portion	AAMI/CN3(PS) compliant	ISO 80369-3 compliant	The same
Geometry of Luer connecting portion	ISO 594-2 compliant	ISO 594-2 compliant	The same
Materials	“DEHP and Latex free materials” (from 510(k) Summary), no further material details provided	DEHP and Latex free polypropylene	The same
Biocompatibility	Established in accordance with ISO 10993	Established in accordance with ISO 10993	The same
Sterility	Not sterile	Not sterile	The same
Usage	Single use	Single use	The same
Manufacturing method	Injection molding	Injection molding	The same
Shelf life	Unknown	3 years	N/A

The Subject Device and the Predicate Device have many identical or similar properties and features. The only differences that exist are related to the exact end connection geometry, for example the predicate has a Male ENFit to Male Luer combination, whereas the subject device has a Male ENFit to Female Luer combination. Similarly, where the predicate has a Female Luer to Female ENFit combination, the subject device has a Male Luer to Female ENFit combination. In addition, although different materials may be used for the predicate and subject devices, the modulus of elasticity in tension for all materials meets the requirements of the relevant FDA-recognised standard. These differences do not have any significant effect on the safety or effectiveness of the subject device.

Conclusion:

Based on the information contained within this submission, it is concluded that the Cedic Enteral ENFit Transition Connectors are substantially equivalent to the identified predicate device already in interstate commerce within the USA.