January 22, 2024

Cair LG
Irving Wiesen
Regulatory Counsel
1, Allée des Chevreuls
Lissieu, Rhône 69380
France

Re: K231299
Trade/Device Name: Nutricair enteral ENFit adapter: ENFit male - stepped/Christmas tree connector
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube And Accessories
Regulatory Class: Class II
Product Code: PIO
Dated: December 22, 2023
Received: December 22, 2023

Dear Irving Wiesen:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
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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)*
K231299

Device Name
Nutricair enteral ENFit adapter: ENFit male – stepped/Christmas tree connector

Indications for Use *(Describe)*
The Nutricair enteral ENFit adapter: ENFit male – stepped/Christmas tree connector is a disposable, sterile medical device intended to be used as an adapter between ENFit connectors and funnel connections, used in enteral nutrition. A doctor, a nurse or the adult laypersons can do enteral feeding. The target population is adults.

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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TAB 5
510(k) Summary

I. Submitter

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Date of Preparation February 27, 2023

II. Device

Trade Name:	Nutricair™ enteral ENFit adapter: ENFit male – stepped/Christmas tree connector
Common Name:	Enteral specific transition connector
Classification Name & Number:	Gastrointestinal Tubes and accessories 21 CFR 876.5980 Class II Product Code: PIO

III. Legally Marketed Predicate Device

Product name: Cedic Enteral Distal End ENFit Transition Connector

510(k) Number: K140581

Manufacturer: Cedic S.r.l

Product Code: PIO

Device Class: Class II

IV. Device Description

General Description of Nutricair™ enteral ENFit adapter: ENFit male – stepped/Christmas tree connector

The Nutricair™ enteral ENFit adapter: ENFit male – stepped/Christmas tree connector is sterile single use device. The adapter presents a ENFit connection in ABS at one extremity and a notched connection (in ABS) at the other extremity. The device has also a female ENFit cap in PEHD attached to the adapter with a link. This device incorporates a male ENFit connector for connection to enteral access device with a female ENFit connector that is compliant to ISO 80369-3. It is provided with a sterility protector.

Reference concerned is NCE104A.

V. Intended Use

The Nutricair enteral ENFit adapter: ENFit male- stepped/Christmas tree connector is a disposable, sterile medical device intended to be used as an adapter between ENFit connectors and funnel connections, used in enteral nutrition. A doctor, a nurse or the adult laypersons can do enteral feeding. The target population is adults.

VI. Substantial Equivalence Discussion

The Nutricair™ enteral ENFit adapter: ENFit male – stepped/Christmas tree connector is substantially equivalent to the currently marketed Cedic Enteral Distal End ENFit Transition Connector. Table 5-1 is a detailed comparison of the Cair adapter to the predicate devices regarding substantial equivalence.

Table 5-1: Device comparison table for Nutricair™ enteral ENFit adapter: ENFit male – stepped/Christmas tree connector and the predicate device.

Design Features/Function	Cedic Enteral Distal End ENFit Transition Connector	Nutricair™ enteral ENFit adapter: ENFit male – stepped/Christmas tree connector	Substantially Equivalent?	Impact on Safety and Performance
Indications for Use	The Cedic Enteral Distal End ENFit Transition Connector is intended for connecting an enteral giving set with an ENFit connector to an enteral catheter with funnel.	The Nutricair™ enteral ENFit adapter: ENFit male – stepped/Christmas tree connector is a disposable, sterile medical device intended to be used as an adapter between ENFit connectors and funnel connections, used in enteral nutrition. A doctor, a nurse or the patient himself can do enteral feeding. The target population is adults	Yes	Equivalent to K140581. There are no differences in indications for use that would impact the safety and performance of the device.
Intended Use	The Cedic Enteral Distal End ENFit Transition Connector is intended for connecting an enteral giving set with an ENFit connector to an enteral catheter with funnel.	The Nutricair™ enteral ENFit adapter: ENFit male – stepped/Christmas tree connector is a disposable, sterile medical device intended to be used as an adapter between ENFit connectors and funnel connections, used in enteral nutrition. A doctor, a nurse or the patient himself can do enteral feeding. The target population is adults.	Yes	Equivalent to K140581. There are no differences in intended use that would impact the safety and performance of the device.
Environment of Use	Hospital - Home	Hospital - Home	Yes	Equivalent to K140581. There are no differences in environment of use that would impact the safety and performance of the device.
Intended Users	A doctor, a nurse or the patient himself can do enteral feeding	A doctor, a nurse or the patient himself can do enteral feeding	Yes	Equivalent to K140581. No impact on safety or performance
Patient Population	Pediatric and adult	Adult	Yes	Equivalent to K140581. No

				impact on safety or performance
Single Use	Yes	Yes	Yes	Equivalent to K140581. No impact on safety or performance
Sterility Condition	Non sterile	Sterile	Yes	Equivalent to K140581. No impact on safety or performance
ENFit Connector	Yes; compliant with ISO 80369-3	Yes; compliant with ISO 80369-3	Yes	Equivalent to K140581. No impact on safety or performance
Marking measures	Yes	Yes	Yes	Equivalent to K140581. No impact on safety or performance
Fluid Leakage: Connector	Tested per ISO 80369-20 and met the standards of 80369-3 for fluid leakage.	Tested per ISO 80369-20 and met the standards of 80369-3 for fluid leakage.	Yes	Equivalent to K140581. No impact on safety or performance
Stress Cracking: Connector	Tested per ISO 80369-20 and met the standards of 80369-3 for stress cracking.	Tested per ISO 80369-20 and met the standards of ISO 80369-3 for stress cracking.	Yes	Equivalent to K140581. No impact on safety or performance
Resistance to separation from axial load: connector	Tested per ISO 80369-20 and met the standards of 80369-3 for resistance to separation from axial load.	Tested per ISO 80369-20 and met the standards of ISO 80369-3 for resistance to separation from axial load.	Yes	Equivalent to K140581. No impact on safety or performance
Resistance to separation from unscrewing: connector	Tested per ISO 80369-20 and met the standards of 80369-3 for separation from unscrewing.	Tested per ISO 80369-20 and met the standards of ISO 80369-3 for separation from unscrewing.	Yes	Equivalent to K140581. No impact on safety or performance

Resistance to overriding: connector	Tested per ISO 80369-20 and met the standards of 80369-3 for resistance to overriding.	Tested per ISO 80369-20 and met the standards of ISO 80369-3 for resistance to overriding.	Yes	Equivalent to K140581. No impact on safety or performance
Disconnection by unscrewing: connector	Tested per ISO 80369-20 and met the standards of 80369-3 for disconnection by unscrewing.	Tested per ISO 80369-20 and met the standards of ISO 80369-3 for disconnection by unscrewing.	Yes	Equivalent to K140581. No impact on safety or performance

VII. Discussion of Differences

There are no substantial differences between the indications for use, use conditions, and use environment of the Nutricair™ enteral ENFit adapter: ENFit male – stepped/Christmas tree connector and Cedic Enteral Distal End ENFit Transition Connector

VIII. Performance Testing

Non-Clinical Tests

Verification and validation testing was performed with the Nutricair™ enteral ENFit adapter: ENFit male – stepped/Christmas tree connector. It was found that enteral adapter is in compliance with the design and performance requirements when tested per the standards listed below.

1. Biocompatibility:
    a. Cytotoxicity per ISO 10993-5:2009
    b. Guinea Pig Maximization Sensitization per ISO 10993-10:2010
    c. Irritation per ISO 10993-10:2010
    d. Acute Systemic Toxicity per ISO 10993-11:2017
    e. Material-Mediated Pyrogenicity per 10993-11:2017
2. Visual Inspections
    a. Visual inspection for the aspect
3. Enteral Device Performance test
    a. Leakage (air and liquids) testing in accordance with ISO 20695:2020

4. Enteral Connector Performance Tests
    a. Fluid leakage per ISO 80369-20:2019
    b. Stress cracking per ISO 80369-20:2019
    c. Resistance to separation from axial load per ISO 80369-20:2019
    d. Resistance to separation from unscrewing per ISO 80369-20:2019
    e. Resistance to overriding per ISO 80369-20:2019
    f. Disconnection by unscrewing per ISO 80369-20:2019
    g. ENFit dimensional verification per ISO 80369-3:2016
5. Risk Analysis per ISO 14971:2019.
    a. Design Failure Modes and Effects Analysis (DFMEA).
6. Usability Analysis per ISO 62366-1:2015.

Clinical Tests

Clinical tests were not required to demonstrate the safety and performance of the Nutricair™ enteral ENFit adapter: ENFit male – stepped/Christmas tree connector. Product functionality has been adequately assessed by non-clinical tests.

Animal Tests

Animal tests were not required to demonstrate the safety and performance the Nutricair™ enteral ENFit adapter: ENFit male – stepped/Christmas tree connector. Product functionality has been adequately assessed by non-animal tests.

IX. Conclusion

The conclusions drawn from the non-clinical tests demonstrate that the Nutricair™ enteral ENFit adapter: ENFit male – stepped/Christmas tree connector are substantially equivalent in safety and effectiveness to the legally marketed devices identified in part III, “Legally Marketed Predicate Devices” of this section.

(End of Section)