October 6, 2023

Cair LG
Irving Wiesen, Esq.
Regulatory Counsel
1, Allée des Chevreuls
Lissieu, Rhône 69380
FRANCE

Re: K231300
Trade/Device Name: Nutricair Enteral Syringe with ENFit
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: Class II
Product Code: PNR
Dated: September 1, 2023
Received: September 5, 2023

Dear Irving Wiesen, Esq.:

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
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)*
K231300

Device Name
Nutricair™ enteral syringe with ENFit®

Indications for Use *(Describe)*
NUTRICAIR™ enteral feeding syringes with ENFit® are disposable, sterile medical devices that are intended for the measurement, the preparation and enteral administration of solutions (hydration, feeding) or medications for neonatal, pediatric and adult patient populations. These devices are intended to be used in clinics and home care settings by:
- health care professionals
- adult laypersons (instructed by/or under the supervision of health care professionals).

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

Official Contact

Name: Anne-Marie FUENTES
Title: Regulatory Affairs Manager
Email: afuentes@cairlgl.fr

CAIR LGL
Address: 1, Allée des Chevreuils
69380 Lissieu, FRANCE

Phone: +33 (0)4 78 43 77 44
Fax: +33 (0)4 78 43 77 09

Date of Preparation September 29th, 2023

II. Device

Trade Name:	Nutricair™ enteral syringe with ENFit®
Common Name:	Enteral Syringe
Classification Name & Number:	Gastrointestinal Tubes and accessories 21 CFR 876.5980 Class II Product Code: PNR

III. Legally Marketed Predicate Device

Product name: Disposable Enteral Feeding Syringe with ENFit Connector

510(k) Number: K193657

Manufacturer: Shinva Ande Healthcare Apparatus Co., Ltd.

Product Code: PNR

Device Class: Class II

IV. Device Description

General Description of Nutricair™ enteral syringe with ENFit

The Nutricair™ enteral syringe with ENFit is sterile, single use device. It is provided in size 10 mL. It consists in a body with ENfit connector in polypropylene, a plunger in polypropylene and a piston seal in isoprene. This device incorporates a female ENFit connector for connection to enteral access device with a male ENFit connector that is compliant to ISO 80369-3. Graduations from 1 to 10 ml are printed on the body. The 10 mL syringe model number is NCE10SE.

V. Intended Use

NUTRICAIR™ enteral feeding syringes with ENFit® are disposable, sterile medical devices that are intended for the measurement, the preparation and enteral administration of solutions (hydration, feeding) or medications for neonatal, pediatric patient and adult patient populations. These devices are intended to be used in clinics and home care settings by:

- health care professionals
- adult laypersons (instructed by/or under supervision of health care professionals).

VI. Substantial Equivalence Discussion

The Nutricair™ enteral syringe with ENFit is substantially equivalent to the currently marketed predicate Disposable Enteral Feeding Syringe with ENFit Connector. Table 5-1 is a detailed comparison of the Cair syringe to the predicate devices regarding substantial equivalence.

Table 5-1: Device comparison table for Nutricair™ enteral syringe with ENFit and the predicate device.

Design Features/Function	Disposable Enteral Feeding Syringe with ENFit Connector (Predicate)	NUTRICAIR™ enteral syringe with ENFit®	Substantially Equivalent?	Impact on Safety and Performance
Indications for Use	The Disposable Enteral Feeding Syringe with ENFit Connector is indicated for use as a dispenser, a measuring device, and a fluid transfer device. It is used to deliver fluids into gastrointestinal system of a patient who is physically unable to eat and swallow. The enteral feeding syringes are intended to be used in clinical or home care setting by users ranging from laypersons (under the supervision of a clinician) to clinicians, in all groups.	NUTRICAIR™ enteral feeding syringes with ENFit® are disposable, sterile medical devices that are intended for the measurement, the preparation and enteral administration of solutions (hydration, feeding) or medications for neonatal, pediatric patient and adult patient populations. These devices are intended to be used in clinics and home care settings by: - health care professionals - adult laypersons (instructed by/or under supervision of health care professionals).	Yes	Equivalent to K193657. There are no differences in indications for use that would impact the safety and performance of the device.

Intended Use	The Disposable Enteral Feeding Syringe with ENFit Connector is indicated for use as a dispenser, a measuring device, and a fluid transfer device. It is used to deliver fluids into gastrointestinal system of a patient who is physically unable to eat and swallow. The enteral feeding syringes are intended to be used in clinical or home care setting by users ranging from laypersons (under the supervision of a clinician) to clinicians, in all groups.	NUTRICAIR™ enteral feeding syringes with ENFit® are disposable, sterile medical devices that are intended for the measurement, the preparation and enteral administration of solutions (hydration, feeding) or medications for neonatal, pediatric patient and adult patient populations. These devices are intended to be used in clinics and home care settings by: - health care professionals - adult laypersons (instructed by/or under supervision of health care professionals).	Yes	Equivalent to K193657. There are no differences in intended use that would impact the safety and performance of the device.
Environment of Use	Hospitals or Home environment – Prescription only	Hospital or home environment – Prescription Only	Yes	Equivalent to K193657. There are no differences in environment of use that would impact the safety and performance of the device.
Intended Users	From Laypersons (under the supervision of a clinician) to clinicians	- health care professionals - adult laypersons (instructed by/or under supervision of health care professionals).	Yes	Equivalent to K193657. No impact on safety or performance
Patient Population	All groups	Neonatology, Pediatric and Adults	Yes	Equivalent to K193657. No impact on safety or performance

Single Use	Yes	Yes	Yes	Equivalent to K193657. No impact on safety or performance
Sterility Condition	Sterile	Sterile	Yes	Equivalent to K193657. No impact on safety or performance
ENFit Connector	Yes; compliant with ISO 80369-3	Yes; compliant with ISO 80369-3	Yes	Equivalent to K193657. No impact on safety or performance
Marking measures	Yes	Yes	Yes	Equivalent to K193657. No impact on safety or performance
Size (mL)[2]	1; 2; 2,5; 3; 5; 10; 20; 30; 30; 50; 60	10	Yes	Similar to K193657. No impact on safety or proper performance
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"	Yes	Equivalent to K193657. No impact on safety or performance
Graduated scale testing	Compliant with ISO 7886-1:2017	Tested and met updated standard ISO 20695:2020 Enteral Feeding Systems – Design and Testing	Yes	Equivalent to K193657. No impact on safety or performance
Barrel testing	Compliant with ISO 7886-1:2017	Tested and met updated standard ISO 20695:2020 Enteral Feeding Systems – Design and Testing	Yes	Equivalent to K193657. No impact on safety or performance
Plunger testing	Compliant with ISO 7886-1:2017	Tested and met updated standard ISO 20695:2020 Enteral	Yes	Equivalent to K193657. No impact

		Feeding Systems – Design and Testing		on safety or performance
Air leakage testing	Compliant with ISO 7886-1:2017	Tested and met updated standard ISO 20695:2020 Enteral Feeding Systems – Design and Testing	Yes	Equivalent to K193657. No impact on safety or performance
Force to operate the piston testing	Compliant with ISO 7886-1:2017	Tested and met updated standard ISO 20695:2020 Enteral Feeding Systems – Design and Testing	Yes	Equivalent to K193657. 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 K193657. 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 K193657. 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 K193657. 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 K193657. 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 K193657. 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 K193657. No impact on safety or performance
ENFit Dimensional Verification	Evaluated per ISO 80369-3 for ENFit dimensional verification.	Evaluated per ISO 80369-3 for ENFit dimensional verification.	Yes	Equivalent to K193657. 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 syringe with ENFit and Disposable Enteral Feeding Syringe with ENFit Connector.

VIII. Performance Testing

Non-Clinical Tests

Verification and validation testing was performed with the NUTRICAIR™ enteral syringe with ENFit. It was found that enteral syringe 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 sharp points or edges
3. Enteral Device Performance test
    a. Graduated capacity in accordance with ISO 20695:2020 and ISO 7886-1:2017

   b. Barrel dimensions in accordance with ISO 20695:2020 and ISO 7886-1:2017
   c. Collar dimensions in accordance with ISO 20695:2020 and ISO 7886-1:2017
   d. Cap-Piston/Piston assembly in accordance with ISO 20695:2020 and ISO 7886-1:2017 (partially)
   e. Cap-Piston/Piston fitting in accordance with ISO 20695:2020 and ISO 7886-1:2017 (partially)
   f. Graduated scale testing in accordance with ISO 20695:2020 and ISO 7886-1:2017
   g. Graduations in accordance with ISO 20695:2020 and ISO 7886-1:2017
   h. Position of the ENFit connector in accordance with ISO 20695:2020 and ISO 7886-1:2017
   i. Leakage (air and liquids) testing in accordance with ISO 20695:2020 and ISO 7886-1:2017
   j. Piston operating force testing in accordance with ISO 20695:2020 and ISO 7886-1:2017
   k. Marking resistance testing in accordance with internal specifications and ISO 7886-1:2017
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 syringe with ENFit. 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 syringe with ENFit. 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 syringe with ENFit 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)