DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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April 5, 2016

Gbuk Enteral Limited
% Leeanne Baker
Regulatory Consultant
Advena Medical
Pure Offices, Plato Close
Warwick, CV34 6WE
United Kingdom

Re: K151503
Trade/Device Name: NUTRICARE - ISOSAF™ Naso-Gastric Feeding Tube
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube and accessories
Regulatory Class: Class II
Product Code: PIF
Dated: February 2, 2016
Received: February 12, 2016

Dear Leeanne Baker,

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 yours,

Herbert P. Lerner -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151503

Device Name
Nutricare ISO-SAF Naso-Gastric Feeding Tube

Indications for Use *(Describe)*
The NUTRICARE ISO-SAF Naso-gastric Feeding Tube device is inserted into the stomach through the nasal cavity for the purpose of supplying a nutritional source for those patients who are unable to feed themselves.

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

for

NUTRICARE – ISOSAF™ NASO-GASTRIC FEEDING TUBE

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3. Date Prepared

20th May 2015

4. Device Identification

Trade/Proprietary Name:	NUTRICARE – ISOSAF™ NASO-GASTRIC FEEDING TUBE
Common/Usual Name:	Tube, feeding
Classification Name:	Gastrointestinal tube and accessories
Classification Regulation:	21 CFR 876.5980
Product Code:	PIF
Device Class:	Class II
Classification Panel:	Gastroenterology/ Urology

5. Legally Marketed Predicate Device(s)

K083210 – CORFLO Anti-IV Enteral Feeding Tube Model Number 20-XXX

6. Device Description

The NUTRICARE ISO-SAF™ Naso-gastric Feeding Tube is an enteral feeding tube designed for continuous or intermittent use. It comprises of radio-opaque polyurethane tube with guide wire set and ENFit connector.

The guide wire set is composed of a rigid guide wire and a male threaded connector, which is inserted into the polyurethane tube. They're depth marks printed on the tube in order to provide reference about the depth of insertion to the practitioner.

The tube is to be inserted through the nasal or oral area and feed down into the alimentary canal system (i.e. stomach area, duodenum or small intestine as intended). The guide wire with male connector is removed when the insertion is done leaving the tube and ENFit connector in situ. Only a female ENFit enteral syringe can be attached to the ENFit connector when in use.

7. Indication for Use Statement

The NUTRICARE ISO-SAF™ Naso-gastric Feeding Tube device is inserted into the stomach through the nasal cavity for the purpose of supplying a nutritional source for those patients who are unable to feed themselves.

8. Substantial Equivalence Discussion

The following table compares the NUTRICARE ISO-SAF™ Naso-gastric Feeding Tube to the predicate device with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5A – Comparison of Characteristics

Manufacturer	**GBUK ENTERAL LTD**	**CORPAC INC.**
Trade Name	**NUTRICARE ISO-SAF™ Naso-gastric Feeding Tube**	**Corflo Anti IV Enteral Feeding Tube**
510(k) Number	-	K083210
Product Code	PIF	FPD
Regulation Number	21 CFR 876.5980	21 CFR 876.5980
Regulation Name	Gastrointestinal tubes and accessories	Gastrointestinal tubes and accessories
Indications for Use	The NUTRICARE ISO-SAF™ Naso-gastric Feeding Tube device is inserted into the stomach through the nasal cavity for the purpose of supplying a nutritional source for those patients who are unable to feed themselves.	The CORFLO® ANTI IV Enteral Feeding tube is intended for use in those patients who require intermittent or continuous tube feedings via the nasogastric or nasoenteric route
Material	Polyurethane	Polyurethane

Manufacturer	GBUK ENTERAL LTD	CORPAC INC.
Trade Name	**NUTRICARE ISO-SAF™ Naso-gastric Feeding Tube**	**Corflo Anti IV Enteral Feeding Tube**
		Rest unknown
Sterile	Yes – Ethylene Oxide	Yes – Ethylene Oxide
Overall Design		
Proximal Connector	Single connector ENFit/ISO 80369-1 compliant	Luer slip two (2) ports
Distal feeding port	Dual openings on opposite sides of tube at offset levels	Single opening
Distal Tip	Continuous with diameter of rest of tube. Extra radiopaque tip	Contoured larger than diameter of rest of tube
Fully Radiopaque throughout length	Yes	Yes
Cm Markings	Numbered markings throughout the length of the tube	Markings through the length of the tube
Overall length	50cm – 120cm	55cm – 140cm
Guidewire	Twisted metal wire with sealed tip ends prior to the feeding port to prevent accidental emergence	Braided metal wire Tip ends prior to the feeding port to prevent accidental emergence
Diameter	6Fr to 12Fr	5Fr to 12Fr
Duration of Use	Short term (up to 30 days)	Short term
Single-Use	Yes	Yes
Shelf Life	3 years	5 years
Latex Free	Yes	Yes
Complies with ISO 10993-1	Cytotoxicity Sensitization Intracutaneous Reactivity	Unknown but assumed to comply as has 510k
ISO 80369-1 ENFIT compliant	Yes	Current product has luer slip connector

9. Non-Clinical Performance Data

The biocompatibility of the NUTRICARE ISO-SAF™ Naso-gastric Feeding Tube has been demonstrated through appropriate *in vivo* and *in vitro* tests on the device. The device has been assessed in accordance with ISO 10993 and does not introduce any additional safety risk over the predicate device.

The following testing has been performed (per AAMI/CN3:2014(PS) where applicable) to support substantial equivalence:

- Falling drop positive pressure liquid leakage – pass
- Stress Cracking – pass
- Resistance to separation from axial load – pass
- Resistance to separation from unscrewing – pass
- Resistance to overriding – pass
- Disconnection from unscrewing – pass

- Tensile testing of the catheter – pass
- Tensile testing of the connectors – pass
- Corrosion testing of guide wire – pass
- Liquid leakage - pass

A comparative study performed demonstrates that the NUTRICARE ISO-SAF™ Naso-gastric Feeding Tube performs as intended and is safe for its intended use when compared with the predicate device.

A Risk Analysis including analysis of the risk of misconnection has been conducted in accordance with EN ISO 14971:2012

As part of demonstrating safety and effectiveness of NUTRICARE ISO-SAF™ Naso-gastric Feeding Tube and in showing substantial equivalence to the predicate device that are subject to this 510(k) submission, GBUK Enteral Limited completed a number of test as detailed below:

- Flow Rate Testing in accordance with EN 1618:1997
- Mechanical Testing of the connector in accordance with AAMI/CN3:2014(PS) and AAMI/CN3:2014(PS), respectively
- Dimensional analysis in accordance with AAMI/CN3:2014(PS)

The NUTRICARE ISO-SAF™ Naso-gastric Feeding Tube passed all testing stated above as shown by the acceptable results obtained.

The NUTRICARE ISO-SAF™ Naso-gastric Feeding Tube complies with the applicable voluntary standards for biocompatibility and sterilization. The device passed all the testing in accordance with national and international standards.

10. Clinical Performance Data

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with a proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the difference between the NUTRICARE ISO-SAF™ Naso-gastric Feeding Tube and the predicate devices do not raise any questions regarding its safety and effectiveness. The NUTRICARE ISO-SAF™ Naso-gastric Feeding Tube, as designed and manufactured, is determined to be substantially equivalent to the

referenced predicate devices.