October 27, 2022

Rockfield Medical
Orla Connaughton
Director of Regulatory Affairs
iHub GMIT, Dublin Road
Galway, Galway H91 DCH9
IRELAND

Re: K222678
Trade/Device Name: Mobility+ Enteral Feeding System
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: Class II
Product Code: PIF, KNT
Dated: August 25, 2022
Received: September 6, 2022

Dear Orla Connaughton:

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/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 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 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, 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)*
K222678

Device Name
Mobility+ Eternal Feeding System

Indications for Use *(Describe)*
Mobility+ is intended to deliver liquid nutrition formula, to an enteral access device (feeding tube) in users aged 2 years and over.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

General Information

Date:	25 August 2022
Classification:	Class II, 21 CFR 876.5980 Gastrointestinal tube and accessories
Product Code:	PIF, KNT
Trade Name:	Mobility+ Enteral Feeding System
Common Name:	Enteral Feeding System
Model Number(s):	MOB1-440 Mobility+ with 440mm Giving Set MOB1-700 Mobility+ with 700mm Giving Set MOB1-1000 Mobility+ with 1000mm Giving Set MOB1-1900 Mobility+ with 1900mm Giving Set
510(k) Owner:	Rockfield Medical GMIT Innovation Hub Dublin Road Galway H91 DCH9 Ireland
Regulatory Contact: Rockfield Medical	Orla Connaughton Regulatory Affairs GMIT Innovation Hub Dublin Road Galway H91 DCH9 Ireland Tel: + 353 91 763 000 Email: orla@rockfieldmd.com

Intended Use

Mobility+ is intended to deliver liquid nutrition formula to an enteral access device (feeding tube) in users aged 2 years and over.

Predicate Device

- Medline Enteral Feeding Sets, K150286

Reference Device

- SMARTez Elastomeric Infusion Pump, K151650

Device Description

The Mobility+ Enteral Feeding System ("Mobility+" or the "System") is a portable, lightweight, non-electronic, disposable enteral feeding system intended to deliver liquid nutrition formula to an enteral access device (feeding tube) in users aged 2 years and over in the clinical or home care settings.
The device is for single patient use, disposable and intended for use over a 24 hour period.

The System has three primary components; food pouch, filling set and giving set.
Food Pouch: The Food Pouch serves as the Mobility+ System's combined reservoir and pump. The pouch consists of a foil container with an internal elastomeric pouch. The Food Pouch can hold up to 500 ml of feed.
Filling Set: The Filling Set is tubing that connects to commercially available nutritional feed from its packaging to the Food Pouch using ENFit connectors. The Filling Set is used to transfer feed from the feed packaging into the Food Pouch, using a syringe.
Giving Set: The Giving Set is tubing that connects the Food Pouch to the implanted feeding tube's ENFit connector. The Giving Sets will be available in a variety of lengths to give a range of feed flow rates.

All connectors in the Mobility+ system comply with the FDA-recognized ENFit standard (ISO 80369-3 and ISO 18250-3).

The Mobility+ may be worn in a bag of choice that can fit the system without kinking the tubing and without squeezing the pouch. The Instructions for use guide the user to place the spout of the pouch within 15cm (6 inches) above or below the stoma when feeding.

Materials

The Mobility+ Enteral Feeding Device is comprised of materials that are commonly used in medical device applications. The biological safety tests performed in accordance with ISO 10993-1 (Biological evaluation of medical devices -- Part 1: Evaluation and testing), for a device which has been categorized as prolonged and indirect contact with the mucosal membrane, demonstrate that the device is biocompatible for its intended use.

The tests performed to demonstrate the biocompatibility of the device were:

- Physical and Chemical Characterization
- Cytotoxicity
- Sensitization
- Irritation / Intracutaneous Reactivity
- Material Mediated Pyrogenicity
- Acute Toxicity
- Subacute Toxicity

Comparison of Technological Characteristics of Mobility+ Enteral Feeding System compared to the Predicate Device (Medline Enteral Feeding System)

The Mobility+ Enteral Feeding Set and the equivalent commercialized predicate device Medline Enteral Feeding Set were evaluated for substantial equivalence. No significant difference in clinical, technical and biological parameters was identified between the Mobility+ Enteral Feeding Set and the predicate device. Both devices have the same intended patient and user populations and intended use; to deliver liquid nutrition formula to an enteral access device (feeding tube). The relevant technological specifications and characteristics are extremely similar, the differences relating to the principle of operation of each device. The Mobility+ Enteral Feeding System is equivalent to the 510(k) cleared SMARTeZ Elastomeric Infusion Pump for the principle of operation (the constriction of the elastomeric fluid reservoir drives the feed solution through the tubing at a flowrate calculated using Hagen-Poiseuille theory, which calculates the volumetric flow rate of a fluid with certain viscosity passing through a cylindrical pipe). The material and biological equivalence is demonstrated via reference to the material used in each device and the technical

and biocompatibility testing which demonstrates equivalence between the devices. Via the comparative analysis and engineering data, the Mobility+ Enteral Feeding System has been shown to be substantially equivalent to the commercialized Medline Enteral Feeding System.

Non Clinical Information

Table 5-1: List of Design Verification Tests

Design Verification Tests	
System Fill	Tube kink resistance
Connector dimensional and functional	Foil seal strength
Pouch valve seal pressure	Spout neck seal
On/Off Clamp functionality	Bond strength
Flowrate under nominal, minimum and overfill conditions	Leak test
Residual Feed remaining in system	Drop test
Multiple use within 24 hour period	Ancillary device compatibility
Temperature performance	Packaging seal strength
Device height relative to stoma	Removal of product from Packaging
Shelf-life testing	Labeling requirements (maintain integrity, adhesion, legible)
IFU requirements (maintain integrity, legible)	UDI (legible)

Table 5-2: List of Design Validation Tests

Design Validation Tests	
Removal of Product from Packaging	Ability to fill
Ability to feed	Ability to flush
Ability to use while mobile	IFU requirements - (easy to understand, language)
Labelling requirements – (easy to understand, language, legible)	

The test results demonstrate that the Mobility+ Enteral Feeding System meets the requirements in the applicable standards and specifications and is substantially equivalent to legally marketed predicate device.

Clinical Information

Clinical studies were not deemed necessary for The Mobility+ Enteral Feeding Set as bench testing was sufficient to demonstrate substantial equivalence by way of comparison to a legally marketed predicate device.

Summary of Substantial Equivalence

Rockfield Medical believes Mobility+ Enteral Feeding System is substantially equivalent to the predicate device, Medline Enteral Feeding Sets, based on the non-clinical literature review as discussed above.