April 12, 2024

Rockfield Medical
℅ Orla Connaughton
CEO
Aztec Medical Ltd
iHub GMIT (ATU), Dublin Road
Galway, Galway H91 DCH9
Ireland

Re: K233034
Trade/Device Name: Mobility+ Enteral Feeding System OTC
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube And Accessories
Regulatory Class: Class II
Product Code: PIF, KNT
Dated: March 12, 2024
Received: March 12, 2024

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 (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)*
K233034

Device Name
Mobility + Enteral Feeding Systems OTC

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:	22 September 2022
Classification:	Class II, 21 CFR 876.5980 Gastrointestinal tube and accessories
Product Code:	PIF, KNT
Trade Name:	Mobility+ Enteral Feeding System OTC
Common Name:	Enteral Feeding System
Model Number(s):	MOB2-0440 Mobility+ with 440mm Giving Set MOB2-0700 Mobility+ with 700mm Giving Set MOB2-1000 Mobility+ with 1000mm Giving Set MOB2-1900 Mobility+ with 1900mm Giving Set
510(k) Owner:	Rockfield Medical iHub GMIT (ATU), Dublin Road Galway H91 DCH9 Ireland
Regulatory Contact:	Orla Connaughton Regulatory Affairs
Rockfield Medical	iHub GMIT (ATU), 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

- Mobility+ Enteral Feeding System, K222678.

Device Description

The Mobility+ Enteral Feeding System OTC ("Mobility+ OTC" 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 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+ Enteral Feeding System OTC 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 the Mobility+ food pouch to deliver 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+ Enteral Feeding System OTC comply with the FDA-recognized ENFit standard (ISO 80369-3 and ISO 18250-3).

The Mobility+ Enteral Feeding System OTC 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.

Non-Clinical Information

The Mobility+ System OTC is the identical device as the predicate. Therefore, all technological characteristics (e.g., design, material, functionality) are identical and non-clinical performance data tests were not repeated. A list of the design verification and design validation test completed are in **Table 3 List of Design Verification Tests** and **Table 4 List of Design Validation Tests**.

Table 3 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	Labelling requirements (maintain integrity, adhesion, legible)
Biological Evaluation	UDI (legible)
IFU requirements (maintain integrity, legible)	

Table 4 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 (**K222678 – Volume 0007 Bench Testing**) demonstrate that the Mobility+ Enteral Feeding System OTC, being identical to the predicate device, meets the requirements in the applicable standards.

The biological safety tests were performed on the predicate device in accordance with ISO 10993-1 (Biological evaluation of medical devices – Part 1: Evaluation and testing). These tests were performed to demonstrate the biocompatibility of the device and are detailed in the predicate submission, **K222768 – Volume 006 Biocompatibility**.

Clinical Information

Clinical studies were not deemed necessary for The Mobility+ Enteral Feeding System OTC 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 OTC is substantially equivalent to the predicate device, Mobility+ Enteral Feeding System (**K222678**).