April 18, 2025

Sky Medical, a.s.
Yulia Surinova
General Manager
Vicenzy 24/2058
Samorin, 931 01
Slovakia

Re: K250481
Trade/Device Name: Extension Feeding Set with ENFit™ Connectors
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube And Accessories
Regulatory Class: Class II
Product Code: PIF
Dated: February 19, 2025
Received: February 19, 2025

Dear Yulia Surinova:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Anthony Lee -S

Anthony Lee, Ph.D., M.B.A.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250481

Device Name

Extension Feeding Set with ENFit™ connectors

Indications for Use *(Describe)*

The Extension Feeding Set with ENFit™ connectors is intended for use as an extension set for a Low-Profile Gastrostomy Replacement Tube (G. Button). It is intended to provide delivery of Enteral Nutrition from administration media with ENFit™ connector and or medication into a single patient, for a maximum of two weeks.
Feeding via an Extension Feeding Set is advocated when nutrition cannot be provided to the patient by mouth and therefore cannot consume an adequate number of calories because of an underlying condition.
Intended patient population: adult, children older than 1 month.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) #:

510(k) Summary

Prepared on: 2025-04-15

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Sky Medical, a.s.
Applicant Address	Vicenzy 24/2058 Samorin 931 01 Slovakia
Applicant Contact Telephone	+421 903 503562
Applicant Contact	Ms. Yulia Surinova
Applicant Contact Email	yulia@med-sky.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Extension Feeding Set with ENFit™ connectors
Common Name	Gastrointestinal tube and accessories
Classification Name	Gastrointestinal Tubes With Enteral Specific Connectors
Regulation Number	876.5980
Product Code(s)	PIF

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K141631	AQUARIUS™ Extension Feeding set	KNT

Device Description Summary

21 CFR 807.92(a)(4)

Description:
The Extension Feeding Set with ENFit™ connectors (Extension Feeding Set), comprises a hollow tube with two different connectors at each end: an ENFit™ connector connecting to an administration media, the other is a secure lock connector for connecting to a gastric feeding device.
The Extension Feeding Set is sterile, single patient use device, consisting of a polyvinylchloride tube, ABS secure lock connector, Tritan ENFit™ connector. The connectors on the proximal end of the extension sets are ENFit™ ISO 80369-3 compliant. The ENFit™ connector allows for connections of enteral specific applications while reducing the likelihood of misconnections to non-enteral devices.
Extension Feeding Sets are available in three lengths: 5 cm (2″), 30.5 cm (12″) or 61 cm (24″). All Extension Feeding Sets are available with either a right-angle secure lock connector or a straight secure lock connector. Both connectors are compatible with G. Button.

Indications for use:
The Extension Feeding Set with ENFit™ connectors is intended for use as an extension set for a Low-Profile Gastrostomy Replacement Tube (G. Button). It is intended to provide delivery of Enteral Nutrition from administration media with ENFit™ connector and or medication into a single patient, for a maximum of two weeks.
Feeding via an Extension Feeding Set is advocated when nutrition cannot be provided to the patient by mouth and therefore cannot consume an adequate number of calories because of an underlying condition.
Intended patient population: adult, children older than 1 month.

Shelf life: 3 years.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The Extension Feeding Set with ENFit™ connectors is intended for use as an extension set for a Low-Profile Gastrostomy Replacement Tube (G. Button). It is intended to provide delivery of Enteral Nutrition from administration media with ENFit™ connector and or medication into a single patient, for a maximum of two weeks.
Feeding via an Extension Feeding Set is advocated when nutrition cannot be provided to the patient by mouth and therefore cannot consume an adequate number of calories because of an underlying condition.
Intended patient population: adult, children older than 1 month.

Indications for Use Comparison 21 CFR 807.92(a)(5)

Both the subject device and the predicate device are intended to be used as extension sets for gastric feeding devices to provide delivery of feeding media from nutrition reservoir into a patient feeding tube.
Slight difference in the wording of the indications for use are not critical to the intended use of the device, the differences do not affect the safety and effectiveness of the device when used as labeled.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device and the predicate device have the same technological characteristics (i.e., design, material, chemical composition) as the predicate device.
There are slight differences in the material used in the predicate device in ENFit™ connectors, tube and clamp. These differences do not have effect on patient and do not increase risks associated with the use of the device.
There are no significant differences in the design, construction and technological processes used during manufacturing of the subject device and the predicate.
Both the subject device and the predicate device properties and have been successfully tested per applicable standards and passed also relevant testing for biocompatibility.
The identified small differences will not raise new question on the new safety and effectiveness of the proposed device as evidence by the provided Substantial Equivalence Comparison.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The following nonclinical testing was conducted to support this submission and determine substantial equivalence:
Visual and dimensional inspection
Small-bore connectors testing
Leakage test
Tensile strength testing
Extension Feeding Set clamp functionality testing
Flow rate testing
Gravity flow test
Packaging testing
Performance testing of connectors
Biocompatibility testing was also completed successfully.

No clinical testing is submitted.