June 18, 2025

HMC Premedical S.p.a.
Danilo Bosetti
QA RA Manager
Via Bosco, 1/3
Mirandola, MO 41037
Italy

Re: K242917
Trade/Device Name: Enteral Drainage System, Enteral Medicine straw
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: Class II
Product Code: PIF
Dated: May 13, 2025
Received: May 16, 2025

Dear Danilo Bosetti:

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 C. Lee, Ph.D, M.B.A.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity, and Transplant Devices
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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)*

K242917

Device Name

Enteral Drainage System
Enteral Medicine straw

Indications for Use *(Describe)*

The Enteral Drainage System is intended to allow the evacuation of excess gas and drainage of gastrointestinal fluids from patients utilizing an enteral device.
The Enteral Medicine Straw is intended for drawing and delivery of medicine to patients through an ENFit syringe.

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) #: K242917

510(k) Summary

Prepared on: 2025-06-17

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	HMC Premedical S.p.a.
Applicant Address	Via Bosco, 1/3 Mirandola MO 41037 Italy
Applicant Contact Telephone	+39 0535 22704
Applicant Contact	Mr. Danilo Bosetti
Applicant Contact Email	FDA@hmcgroup.it

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Enteral Drainage System, Enteral Medicine straw
Common Name	Gastrointestinal tube and accessories
Classification Name	Gastrointestinal Tubes With Enteral Specific Connectors
Regulation Number	21 CFR 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
K142012	Farrell Valve System with Equilibrium Technology and Enfit Enter	PIF
K190310	U Deliver Bolink ENFit Enteral Feeding Sets	PIF

Device Description Summary

21 CFR 807.92(a)(4)

The Enteral Drainage System and the Enteral Medicine straw are intended to be used during enteral nutrition treatments in combination with enteral feeding tubes, syringes and other compatible enteral medical devices.

The Enteral Drainage System is intended to allow the evacuation of excess gas and drainage of gastrointestinal fluids from patients utilizing an enteral device.
The device consists of:
- a bag in DEHP FREE PVC, equipped with a hydrophobic 3µm filter to allow gas escape;
- two short PVC tubes (5-6 cm) on top and bottom of the bag; the bottom one is equipped with a male enteral connector, and the top one with a female enteral connector that is capped off with an ENFit-compatible cap;
- a clamp to regulate the fluid flow, placed over the bottom tube.

It is available in five sizes, depending on the volume of the bag included in the device:
MED50LU, Enteral drainage bag 50 ml;
MED100LU, Enteral drainage bag 100 ml;
MED250LU, Enteral drainage bag 250 ml;
MED500LU, Enteral drainage bag 500;
MED1000LU, Enteral drainage bag 1000 ml.
The device is connected to the nasogastric or naso-jejunal feeding tube between feeding sessions to allow the drainage of stomach or intestinal fluids and gasses in excess. The transparency of the materials allows for constant monitoring and visualization of drained fluids. The bag must be placed at a lower level than the patient's stomach and also acts as a venting device.

The Enteral Medicine straw, coded C005LU, is intended for drawing and delivery of medicine to patients through an ENFit enteral syringe. It consists of a male enteral connector (that allows the connection to a compatible enteral syringe) and a tubing in thermoplastic polyurethane.
Once the fluid is drawn up from the container into the syringe, the cannula must be disconnected, and the syringe can then be connected to another medical device (normally, a feeding tube or a gastrostomy tube) to administer its content to the patient.

All enteral connections of the subject devices are designed to avoid for inadvertent delivery of enteral feedings through the intravenous route. i.e., the devices cannot be connected to devices endowed with a luer connector.
The devices are sterilized with Ethylene Oxide (EO).
These devices are targeted to neonatal, pediatric and adult patients, with compromised or limited gastric motility; they are for single patient use and can be reused multiple times within a twenty-four-hour period, after which they are to be replaced.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Enteral Drainage System is intended to allow the evacuation of excess gas and drainage of gastrointestinal fluids from patients utilizing an enteral device.
The Enteral Medicine Straw is intended for drawing and delivery of medicine to patients through an ENFit syringe.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Enteral Drainage System:
The indications for use of the subject device are included in those of the predicate device. Both devices are intended for stomach decompression during enteral feeding procedure. The subject device has a narrower intended use in respect to the predicate device, since it is only intended for drainage: its intended use is included in the wider intended use of the predicate device.

Enteral Medicine Straw:
The subject device and the predicate are both intended to draw fluid solutions and deliver them to a patient through an enteral access device. The indications for use of the predicate device do not expressly mention the use for drawing, but this is implicitly included in the intended use of the device (the device draws the solution from a container and then it delivers it). Thus, their intended use is substantially equivalent.
The predicate device is intended to be directly connected to an ENFit feeding tube, and solution collected from the container is delivered to the patient by gravity; as for the subject devices, the solution is drawn from the container by means of an ENFit enteral syringe and then delivered to the patient's ENFit enteral access. The use of the ENFit syringe allows to measure and fractionate the doses of solution drawn from the container and to be delivered to the patient.This difference in the principle of operation does not change the intended use of the devices and does not have any significant effect on the safety or effectiveness of the subject device, also considering that the subject device is prescription use only (to be used by adequately trained staff), while the predicate device is intended for over-the-counter use.

Technological Comparison

21 CFR 807.92(a)(6)

Enteral Drainage System:
The subject device has similar technological characteristics and design as the predicate device, as they both include a vented bag, tubing with clamps and male/female enteral connectors. They operate in a similar way, allowing the excess gas and fluids to evacuate in the vented bag.
There is a slight difference in the tube length and in the inner and outer diameter of the tube. The difference is not relevant because the fluid flow is determined by the inner diameter of the enteral connector. Performance tests were conducted on the proposed device and the test results of tube part showed that the performance of the proposed device met the pre-determined acceptance criteria. Therefore, the difference on tube size will not raise new issues of safety and effectiveness of the proposed device.
The proposed device is available in 5 different configurations according to their bag volume, while the predicate device is offered only with a 500 mL bag. The air vent filter is the same for all bag sizes.
The bag is only intended to collect discarded fluids and its different capacity has no effects on the operating modalities of the device.
Both the subject and the predicate device are made of PVC and ABS. The results of biocompatibility testing performed on the proposed device show no adverse effects.

Enteral Medicine Straw:
The subject device has similar technological characteristics and design as the predicate device, all including an enteral connector and a

path through which solutions flow.
The proposed device has a simpler design than the predicate device (which includes a cross spike connector and a clamp) and must be connected to an ENFit enteral syringe - by means of which the solution is drawn from the container and subsequently delivered to the patient's enteral access - whereas the predicate device directly connects the fluid container to the feeding tube.
Moreover, the subject device carries a male enteral connector that matches with the female ENFit connector of the syringe, while the predicate device has a female ENFit connector that matches with the male ENFit connector of the feeding tubes. However , these minor differences do not affect the safety or effectiveness of the proposed devices as shown by the performance tests conducted on the proposed device.
Both the subject and predicate devices are to be connected to enteral end fittings compliant with ISO 80369-3 ('ENFit' connections).
The proposed device is manufactured with raw materials which are similar to those used for the predicate device, well known and largely used for similar devices already cleared under the same product code.
The results of biocompatibility testing performed on the proposed device show no adverse effects.

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

Nonclinical tests were conducted to demonstrate substantial equivalence to the predicate devices. The test results demonstrated that the proposed devices comply with the applicable sections of the standards cited below.

Biocompatibility:
The materials used to manufacture the subject devices are similar to those used for the predicate devices. All the materials used to manufacture the subject device are largely used for other legally marketed devices under the same product code.
Biocompatibility has been tested according to the requirements of ISO 10993 series.
The subject devices meet requirements for ISO 10993-1 as the predicate devices.
Material-Mediated Pyrogenicity was also tested according to USP <151>.

Performance tests:
Non-clinical tests were performed to confirm that differences in materials and technological characteristics do not affect the safety or effectiveness of the devices.
Misconnection testing, leak testing and tensile strength testing were performed.
Tests were conducted according to:
- ISO 80369-3:2016 and ISO 80369-20:2015 (at time 0, after accelerated aging and after simulated distribution) on male and female connectors;
- ISO 80369-3:2016 - Point 5 to verify the dimensional requirements for enteral small-bore connectors;
- ISO 20695:2020 for Enteral nutrition

The integrity of the device packaging was tested according to:
ISO 11607-1:2019 "Packaging for terminally sterilized medical devices – Requirements for materials, sterile barrier systems and packaging systems";
ASTM F1980-16 "Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices";
ASTM D4332-14 "Standard Practice for Conditioning Containers, Packages, or Packaging Component for Testing";
ASTM D 4169-16 "Standard Practice for Performance Testing of Shipping Containers and Systems";
ASTM F 1929-15 "Standard Test Method For Detecting Seal Leaks In Porous Medical Packaging By Dye Penetration".

Animal and clinical testing was not applicable to support substantial equivalence

The conclusions drawn from the nonclinical testing on the subject devices demonstrate that the devices are as safe, as effective, and performs as well as the correspondent legally marketed predicate devices