July 1, 2026

CHIRANA T.Injecta,a.s.
Rastislav Broska
Quality Manager
Nám.Dr.A.Schweitzera 194
Stará Turá, 916 01
Slovakia

Re: K252483
Trade/Device Name: Enteral Syringe (20ml, 60ml)
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube And Accessories
Regulatory Class: Class II
Product Code: PNR
Dated: May 26, 2026
Received: June 1, 2026

Dear Rastislav Broska:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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., MBA
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)*
K252483

Device Name
Enteral Syringe (20ml, 60ml)

Indications for Use *(Describe)*
Enteral Syringe is indicated for use as a dispenser, a measuring device and a fluid transfer device. Enteral Syringe delivers fluids into the gastrointestinal system of a patient who is physically unable to eat and swallow. Enteral Syringe is intended to be used in clinical or home care settings by users ranging from laypersons (under the supervision of a clinician) to clinicians in all age groups.

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) SUMMARY

Submitter's Name:	CHIRANA T. Injecta, a.s.
Submitter's Address:	Nám. Dr. Schweitzera 194 916 01 Stará Turá Slovak Republic
Submitter's Telephone:	421-32-770-9972
Contact Person:	Rastislav Broska 00421 910 955 937 rbroska@vitrexmg.com
Date Summary was Prepared:	May 26, 2026
Trade or Proprietary Name:	Enteral Syringe
Common or Usual Name:	Piston Syringe
Classification:	Class II per 21 CFR §876.5980
Product Code:	PNR
Classification Panel:	Gastroenterology/Urology

DESCRIPTION OF THE DEVICES SUBJECT TO PREMARKET NOTIFICATION:

Enteral Syringes

The subject Enteral Syringes consist of violet piston, gasket and barrel with printed scale which is graduated in milliliters and Enfit connector. The piston has molded graduation on surface for inspection of drug volume in syringe. The Enfit connector is manufactured according to ISO 80369-3:2016 and is centered on the barrel axis for 20ml and 60ml syringe. The Enfit connector ensures the strong and safe connection of syringe with enteral accessories having Enfit connection. The syringes are sterile, single use and non-toxic. These devices operate on the principles of a piston syringe. Plunger movement in the barrel deliver the fluids into the gastrointestinal system of a patient and the flow is controlled manually.

INDICATIONS FOR USE

Enteral Syringe is indicated for use as a dispenser, a measuring device and a fluid transfer device.

Enteral Syringe delivers fluids into the gastrointestinal system of a patient who is physically unable to eat and swallow. Enteral Syringe is intended to be used in clinical or home care settings by users ranging from laypersons (under the supervision of a clinician) to clinicians in all age groups.

TECHNOLOGICAL CHARACTERISTICS

Materials:

The materials of the syringes include polypropylene (barrel, piston), latex free synthetic rubber gasket and medical grade silicone.

Sizes:

The Enteral Syringe includes size of 20mL and 60 mL.

Principles of Operation:

The Enteral syringe by plunger movement in the barrel delivers the fluids into the gastrointestinal system of a patient who is physically unable to eat and swallow. The flow is controlled manually.

The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically the following characteristics are identical between the subject and predicates:

- Indications for Use
- Sizes
- Materials of manufacture
- Structural support mechanism

The subject **Enteral Syringe** for single use is nearly identical to the previously cleared predicate device – Enteral Feeding Syringes with Enfit Connectors, 510(k) number K182649, in indications for use, design, sizes, materials, technological characteristics, biocompatibility, and sterilization.

Item	**Subject Device**	**Predicate Device K182649**	**Remark**
Device Name	Enteral Syringe	Enteral Feeding Syringe with ENFit Connector	
Product Code	PNR	PNR	Same
Regulation No.	21 CFR 876.5980	21 CFR 876.5980	Same
Class	Class II	Class II	Same
Indications for Use	Enteral Syringe is indicated for use as a dispenser, a measuring device, and a fluid transfer device. It is used to deliver fluids into the gastrointestinal system of a patient who is physically unable to eat and swallow. The enteral syringes are intended to be used in clinical or home care settings by users ranging from laypersons (under the supervision of a clinician) to clinicians in all age groups.	Enteral Feeding Syringe with ENFit Connector is indicated for use as a dispenser, a measuring device, and a fluid transfer device. It is used to deliver fluids into the gastrointestinal system of a patient who is physically unable to eat and swallow. The enteral syringes are intended to be used in clinical or home care settings by users ranging from laypersons (under the supervision of a clinician) to clinicians in all age groups.	Same

Device	Design	barrel, plunger, piston	barrel, plunger, piston	Same
	Connector Types	ENFit connector	ENFit connector	Same
	Sizes	20ml, 60ml	1ml, 3ml, 6ml, 12ml, 20ml, 35ml, 60ml	Different Note 1
Materials	Barrel	Polypropylene (PP)	Polypropylene (PP)	Same
	Plunger	Polypropylene (PP), color additives	Polypropylene (PP), color additives	Same
	Gasket	Polyisoprene	Polyisoprene	Same
	Lubricants	Polydimethylsiloxane	Not known	Different Note 2
Use		Prescription use	Prescription use	Same
Single Use		Yes	Yes	Same
Operation Mode		Manual use	Manual use	Same
Syringe Performance		Complied with: ISO 7886-1 ISO 80369-3 ISO 80369-20	Complied with: ISO 7886-1 ISO 80369-3 ISO 80369-20	Same
Biocompatibility		Conforming to ISO 10993 series Cytotoxicity Irritation Skin sensitization	Conforming to ISO 10993 series Cytotoxicity Irritation Skin sensitization	Same
Sterilization		EO (ethylene gas) to SAL=10^{-6}	EO (ethylene gas) to SAL=10-6	Same

Note 1.
The predicate device includes additional syringe sizes (1 mL, 3 mL, 6 mL, 12 mL, and 35 mL) that are not included in the subject device. The subject device is limited to 20 mL and 60 mL configurations only. The difference in available sizes does not alter the intended use, fundamental design, materials, technological characteristics, or principles of operation of the device. The subject device utilizes the same ENFit connector design and complies with the same applicable performance standards as the predicate device. Therefore, this difference does not affect the safety or effectiveness of the subject device and does not raise different questions of safety and effectiveness.

Note 2.
The lubricant material used in the predicate device is not publicly specified. The subject device uses polydimethylsiloxane lubricant, which is a commonly used lubricant material for three-part syringes and is compatible with the applicable performance requirements of ISO 7886-1. Both the subject and predicate devices comply with the same applicable performance standards, including ISO 7886-1, ISO 80369-3, and ISO 80369-20. Therefore, the difference in lubricant identification does not affect the intended use, technological characteristics, performance, safety, or effectiveness of the subject device and does not raise different questions of safety and effectiveness.

PERFORMANCE DATA

The subject device, **Enteral Syringes** have been tested in the following test modes

- EN ISO 7886-1:2018 Sterile hypodermic syringe for single use- Part 1: Syringes for manual use
- ISO 80369-3:2016 Small-Bore Connectors for Liquids and Gases in Healthcare Applications-Part 3: Connectors for Enteral Applications
- Cytotoxicity (ISO 10993-5)
- Sensitization (ISO 10993-10)
- Irritation (ISO 10993-10)
- Intracutaneous reactivity (ISO 10993-10)
- Material mediated pyrogenicity (ISO 10993-11/USP 151)
- Acute systemic toxicity (ISO 10993-11)

CONCLUSION

The subject Enteral syringes are substantially equivalent to the predicate devices in intended use, operating principle, technology, design, materials and performance.