April 17, 2026

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

Re: K252279
Trade/Device Name: Sterile Hypodermic Syringe for Single Use (20ml, 30ml, 50ml, 60ml)
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: February 20, 2026
Received: March 13, 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,

Shruti N. Mistry -S

Shruti Mistry
Assistant Director
DHT3C: Division of Drug Delivery and General Hospital Devices, and Human Factors
OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252279

Please provide the device trade name(s).

Sterile Hypodermic Syringe for Single Use (20ml, 30ml, 50ml, 60ml)

Please provide your Indications for Use below.

Sterile Hypodermic Syringes for Single Use are intended to be used for medical purposes for injection or withdraw fluids from body.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

K252279 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:	April 17, 2026
Trade or Proprietary Name:	Sterile Hypodermic Syringe for Single Use (20ml, 30ml, 50ml, 60ml)
Common or Usual Name:	Piston Syringe
Classification:	Class II per 21 CFR §880.5860
Product Code:	FMF
Classification Panel:	Division of Drug Delivery, General Hospital Devices, and Human Factors

DESCRIPTION OF THE DEVICES SUBJECT TO PREMARKET NOTIFICATION:

The **Sterile Hypodermic Syringes for Single Use** type consist of piston, gasket and barrel with printed scale which is graduated in milliliters. Material of barrel allows to control the position of the piston according to the scale. Syringes with Luer or Luer-Lock are manufactured according to EN ISO 80369-7:2021. The cone of all Luer-Lock syringes is centered on the barrel axis. The Luer-Lock connector ensures the connection of syringe with needle or extension line.

INDICATIONS FOR USE

Sterile Hypodermic Syringes for Single Use are intended to be used for medical purposes for injection or withdraw fluids from body.

TECHNOLOGICAL CHARACTERISTICS

Materials:

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

Sizes:

The Sterile hypodermic syringe includes size of 20mL, 30mL, 50ml and 60 mL.

Principles of Operation:

The Sterile Hypodermic Syringe by plunger movement in the barrel inject or withdraw fluids from body.

The subject and predicate device has nearly identical technological characteristics and the minor differences do not raise any new or different questions of safety and effectiveness when compared

to the predicate device. Specifically, the following characteristics are identical between the subject and predicate:

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

The subject **Sterile Hypodermic Syringes for Single Use** are nearly identical to the previously cleared predicate device - Sterile Hypodermic Syringes for Single Use, 510(k) number K213811 in intended use, design, sizes, materials, technological characteristics, biocompatibility, and sterilization.

Table 3-1: Predicate Comparison Table

Item		Subject Device	Predicate Device K213811	Remark
Device Name		Sterile Hypodermic Syringe for Single Use	Sterile Hypodermic Syringes for Single Use	
Product Code		FMF	FMF	Same
Regulation No.		21 CFR 880.5860	21 CFR 880.5860	Same
Class		Class II	Class II	Same
Indications for Use		Sterile hypodermic syringe for single use is intended to be used for medical purposes for injection or withdraw fluids from body.	The Sterile Hypodermic Syringes for Single Use are intended to be used for medical purposes on adult and pediatric population to inject fluids into or withdraw fluids from the body.	Different Comment 1
Design	Design	barrel, plunger, piston	barrel, plunger, piston	Same
	Connector Types	Luer Lock/ Luer Slip	Luer Lock/ Luer Slip	Same
	Cone Placement	Luer Lock: centric Luer Slip (50 ml): eccentric	Luer Lock: centric Luer Slip: centric and eccentric (≥ 5 mL)	Different Comment 2
	Sizes	20ml, 30ml, 50ml, 60ml	10ml, 20ml, 30ml, 50mL, 60ml	Different Comment 3
Materials	Barrel	Polypropylene (PP)	Polypropylene (PP)	Same
	Plunger	Polypropylene (PP)	Polypropylene (PP)	Same
	Gasket	Polyisoprene rubber	Polyisoprene rubber	Same
	Lubricants	Polydimethylsiloxane	Polydimethylsiloxane	Same
Use		Prescription use	Prescription use	Same
Single use		Yes	Yes	Same
Syringe Performance		Complied with ISO 7886-1:2017	Complied with ISO 7886-1:2017	Same
Biocompatibility		Conforming to ISO 10993-1:2018	Conforming to ISO 10993-1:2018	Same
Shelf-life		5 years	5 years	Same
Sterilization		EO (ethylene gas) to SAL=10^{-6}	EO (ethylene gas) to SAL=10-6	Same

Comment 1.
The omission of explicit patient population in the subject device indications for use does not limit

or expand the intended use compared to the predicate device. The subject device is not intended for a different patient population, and no changes in design, materials, or performance are associated with this wording difference.

Comment 2.
The cone placement of the subject device syringes is identical to that of the corresponding predicate device syringes of the same size. Specifically, both the subject and predicate Luer Lock syringes have a centric cone placement. For Luer Slip syringes, predicate devices above 5 mL (including 50 mL) have an eccentric cone placement, which is consistent with the subject device 50 mL syringe. These configurations are consistent with established design conventions for syringes of similar type and volume and do not introduce any new questions of safety or effectiveness when compared to the predicate device.

Comment 3.
The subject device product range does not include a 10 mL syringe size, whereas the predicate device (K213811) includes a 10 mL configuration. This difference represents a reduced size offering rather than a modification of design, materials, or performance characteristics. The omission of the 10 mL size does not impact the technological characteristics, intended use, or fundamental operating principles of the subject device. Therefore, this difference does not raise new questions of safety and effectiveness when compared to the predicate device.

PERFORMANCE DATA

The subject device, **Sterile Hypodermic Syringes for Single Use**, have been tested in the following test modes:

- Air leakage past syringe piston during aspiration (EN ISO 7886-1:2018, art.13.2, Annex. B)
- Liquid leakage at syringe piston under compression (EN ISO 7886-1:2018, art.13.2, Annex. D)
- Forces required to operate the piston (EN ISO 7886-1:2018, Annex. E)
- Seal strength paper - foil (EN 868-5:2018)
- Sterile barrier test (EN ISO 11607-2:2020)
- Residual (dead space) volume test (EN ISO 7886-1:2018, 13.1, Table 1, Annex C)
- Nominal volume test (EN ISO 7886-1:2018, Table No.1)
- Luer connector tests (ISO 80369-7:2021)
- Cytotoxicity (ISO 10993-5)
- Skin sensitization (ISO 10993-10)

- Skin Irritation (ISO 10993-10)
- Intracutaneous reactivity (ISO 10993-10)
- Material mediated pyrogenicity (ISO 10993-11/USP 151)
- Acute systemic toxicity (ISO 10993-11)
- Hemocompatibility (ISO 10993-4:2017)

The results of this non-clinical testing show that the performance of the subject Hypodermic Syringes is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The subject Sterile Hypodermic Syringe for Single Use is substantially equivalent to the predicate device in intended use, operating principle, technology, design, materials and performance.