December 24, 2024

CHIRANA T. Injecta
℅ Nathan Wright
Engineer & Regulatory Specialist
Empirical Technologies
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K242434
Trade/Device Name: Insulin Syringes
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, FMI
Dated: November 26, 2024
Received: November 26, 2024

Dear Nathan Wright:

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,

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

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.

510(k) Number *(if known)*
K242434

Device Name
Insulin Syringes

Indications for Use *(Describe)*

The Insulin Syringes are intended for subcutaneous injection of U100 insulin or U40 insulin.

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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K242434 -510(K) SUMMARY

Preparation Date:	December 24, 2024
Submitter Name:	CHIRANA T. Injecta, a.s. Nám. Dr. Schweitzera 194 916 01 Stará Turá Slovak Republic Tel.: +421/32/7709 991
Contact Person: Telephone Number: Email Address:	Nathan Wright, RAC Engineer & Regulatory Specialist, Empirical Technologies 719-351-0248 nwright@empiricaltech.com
Trade Name:	Insulin Syringes
Review Panel:	Drug Delivery and General Hospital Devices, and Human Factors (DHT3C)
Regulation Name:	Piston Syringe
Regulation Number:	21 CFR 880.5860
Product Code:	FMF
Device Class:	Class II
Regulation Name:	Hypodermic Single Lumen Needle
Regulation Number:	21 CFR 880.5570
Product Code:	FMI
Device Class:	Class II
Predicate Device:	K201044, CHIRANA® Insulin Syringes (CHIRANA T. Injecta, a.s.)
Reference Device:	K233794, Insulin Syringe (SPM Medicare Pvt. Ltd.)
Reference Device:	K161170, BD Eclipse Hypodermic Needle (Becton, Dickinson and Company)

Purpose

The CHIRANA® Insulin Syringes are being submitted in this special 510(k) with modifications to the previously cleared CHIRANA® Insulin Syringes (K201044) to update the syringe packaging options, add new size options, and rename the syringe set.

Device Description

The Insulin Syringes are 0.3 mL, 0.5 mL, or 1.0 mL syringes designed for subcutaneous injection of a desired dose of insulin. The Insulin Syringes consist of a graduated barrel, plunger rod and needle/hub assembly. It is available in various needle gauge sizes (25G, 26G, 27G, 28G, 29G, 30G and 31G) and various needle lengths (6mm, 8mm, and 12.7mm). The Insulin Syringes are sterile, single use, and non-toxic. These devices operate on the principles of a piston syringe. The following are the list of syringe and needle combinations offered.

Type	Syringe Volume	Needle Gauge	Needle Length(s)	Clearance Status
Insulin U40	0.3 mL	29G	12.7 mm	New Size
	0.3 mL	30G	12.7 mm	New Size
	0.5 mL	29G	12.7 mm	New Size
	0.5 mL	30G	12.7 mm, 8 mm	New Size
	1 mL	27G	12.7 mm	Cleared in K201044
	1 mL	29G	12.7 mm	New Size
	1 mL	30G	12.7 mm, 8 mm, 6 mm	New Size
Insulin U100	0.3 mL	29G	12.7 mm	Cleared in K201044
	0.3 mL	29G	8mm	New Size
	0.3 mL	30G	12.7 mm, 8 mm	New Size
	0.3 mL	30G	6 mm	Cleared in K201044
	0.3 mL	31G	8 mm, 6 mm	Cleared in K201044
	0.5 mL	27G	12.7 mm	New Size
	0.5 mL	29G	12.7 mm	Cleared in K201044
	0.5 mL	29G	8 mm	New Size
	0.5 mL	30G	12.7 mm	New Size
	0.5 mL	30G	8 mm, 6 mm	Cleared in K201044
	0.5 mL	31G	8 mm, 6 mm	Cleared in K201044
	1 mL	25G	12.7 mm	New Size
	1 mL	26G	12.7 mm	New Size
	1 mL	27G	12.7 mm	Cleared in K201044
	1 mL	27G	8 mm	New Size
	1 mL	28G	12.7 mm, 8 mm	New Size

1 mL	29G	12.7 mm, 8 mm	Cleared in K201044
1 mL	30G	12.7 mm, 8 mm	Cleared in K201044
1 mL	30G	6 mm	New Size
1 mL	31G	8 mm, 6 mm	Cleared in K201044
1 mL	Luer		Cleared in K201044

Indications for Use

The Insulin Syringes are intended for subcutaneous injection of U100 insulin or U40 insulin.

Characteristic	**Subject Device** Insulin Syringes	**Predicate Device** CHIRANA® Insulin Syringes K201044
Indications for Use	The Insulin Syringes are intended for subcutaneous injection of U100 insulin or U40 insulin.	The CHIRANA® Insulin Syringes are intended for subcutaneous injection of U100 insulin or U40 insulin.
Prescription Only or Over the Counter	Both OTC and Rx Use	Over the Counter

The expanded use of the Insulin Syringes to include prescription use does not raise any new questions for safety and effectiveness when compared to the predicate device since their use would be under the authorization of a licensed practitioner. Other Insulin Syringes with the same indicated use as the subject, such as the SPM Medicare Insulin Syringes (K233794), have both prescription use and over-the-counter use.

Technological Characteristics

The table below includes a comparison of the technological characteristics between the new device and those of the predicate device:

		Insulin Syringes	**CHIRANA® Insulin Syringes**
Manufacturer		CHIRANA T. Injecta	CHIRANA T. Injecta
510(k) Number		Subject	K201044
Product Code		FMF, FMI	FMF, FMI
Design	Design	graduated barrel, plunger rod and needle/hub assembly	graduated barrel, plunger rod and needle/hub assembly
	Volume	0.3mL, 0.5mL, 1mL	0.3mL, 0.5mL, 1mL
	*Gauge	25G, 26G, 27G, 28G, 29G, 30G, 31G	27G, 29G, 30G, 31G
	Length	6 mm, 8 mm, 12.7 mm	6 mm, 8 mm, 12.7 mm
Materials	Needle	Stainless Steel 304	Stainless Steel 304
	Barrel	Polypropylene	Polypropylene
	Plunger	Polypropylene	Polypropylene
	Hub Tip	Polystyrene	Polystyrene
	Needle Cap	Polyethylene	Polyethylene
	Protective End Cap	Polyethylene	Polyethylene
	Cannula Lubricant	Medical Grade Silicone	Medical Grade Silicone
Biocompatibility		Conforming to ISO 10993-1	Conforming to ISO 10993-1
Sterilization		EO (ethylene gas) to SAL=10^{-6}	EO (ethylene gas) to SAL=10^{-6}

*The additional subject syringe sizes being added in this 510(k) include needle gauges 25G, 26G, and 28G which were not part of the previously cleared set. The new needle gauges fall within the range of needle sizes which the FDA has cleared for the same general use, such as the BD Eclipse Hypodermic Needle (K161170) ranging from18G to 30G and indicated for the general purpose for injection and aspiration of fluid (implicit of insulin) into the body below the skin.

Performance Testing

The sterile Insulin Syringes described in this summary were tested with the following methods:

ISO 8537 Third edition: Sterile single-use syringes, with or without needle, for insulin
ISO 7886-1 Second edition: Sterile hypodermic syringes for single use – Part 1: Syringes for manual use
ISO 9626 Second edition: Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
ISO 7864 Fourth edition: Sterile hypodermic needles for single use - Requirements and test method

Sterility, Shipping and Shelf-Life

- Sterilization validation per ISO 11135 Second edition: Sterilization of health-care products - Ethylene oxide -Requirements for

the development, validation and routine control of a sterilization process for medical devices

- Packaging Stability
- Shelf life of 5 years for single unit packaging is validated using the FDA recognized standard ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Conclusions

The differences in packaging options, sizes, and use between the subject device and the predicate device do not raise any new or different questions of safety or effectiveness. The subject Insulin Syringes are substantially equivalent to the CHIRANA® Insulin Syringes (K201044) with respect to the indications for use, target populations, treatment method, and technological characteristics.