January 18, 2022

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

Re: K201044
Trade/Device Name: CHIRANA Insulin Syringes
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, FMI
Dated: December 14, 2021
Received: December 15, 2021

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

CAPT Alan Stevens
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201044

Device Name
CHIRANA® Insulin Syringes

Indications for Use *(Describe)*
The CHIRANA® 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

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K201044 510(K) SUMMARY

Preparation Date:	January 18, 2022
Submitter Name:	CHIRANA T. Injecta, a.s. Nám. Dr. Schweitzera 194 916 01 Stará Turá Slovak
Contact Person:	Nathan Wright Engineer & Regulatory Specialist, Empirical Testing Corp.
Telephone Number:	719-351-0248
Fax Number:	N/A
E-mail Address:	nwright@empiricaltech.com
Trade Name:	CHIRANA® Insulin Syringes
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:	K190002, Sterile Insulin Syringe for Single use, with needle (Shanghai Kohope Medical Devices Co., Ltd)

Device Description

The CHIRANA® Insulin Syringes are a 0.3mL, 0.5mL, or 1.0mL syringes designed for subcutaneous injection of a desired dose of insulin. The CHIRANA® Insulin Syringes consist of a graduated barrel, plunger rod and needle/hub assembly. It is available in various needle gauge sizes (27G, 29G, 30G and 31G) and various needle lengths (6mm, 8mm, and 12.7mm). The CHIRANA® 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.

Insulin Type	Syringe Volume	Needle Gauge	Needle Diameter
Insulin U40	1 mL	29G	12.7 mm
Insulin U100	1 mL	27G	12.7 mm
		29G	8 mm
		29G	12.7 mm
		30G	12.7 mm
		30G	8 mm
		31G	8 mm
		31G	6 mm
Insulin 100	0.5 mL	29G	12.7 mm
		30G	12.7 mm
		30G	8 mm
		31G	8 mm
		31G	6 mm

Insulin Type	Syringe Volume	Needle Gauge	Needle Diameter
Insulin 100	0.3 mL	29G	12.7 mm
		30G	12.7 mm
		31G	8 mm
		31G	6 mm

Indications for Use

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

Characteristic	**Predicate Device** Shanghai Kohope Medical Devices Co., Ltd Syringes for Single use, with needle K190002	**Subject Device** CHIRANA® Insulin Syringes K201044
Indications for Use	The sterile Insulin Syringe for Single use with needle, with the calibration unit of insulin for U-100, is a device intended for medical purposes for the manual aspiration of insulin, and for the injection of insulin into parts of insulin into parts of the body below the surface skin. The sterile Insulin Syringe for Single use with needle, with the calibration unit of insulin for U-40, is a device intended for medical purposes for the manual aspiration of insulin, and for the injection of insulin into parts of insulin into parts of the body below the surface skin.	The CHIRANA® Insulin Syringes are intended for subcutaneous injection of U100 insulin or U40 insulin.
Prescription Only or Over the Counter	Over the Counter	Over the Counter

Discussions of differences in Indications for Use statement

There are only editorial differences to the indications for use statement between the predicate and the subject device which do not change the indications.

Technological Characteristics

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

		CHIRANA® Insulin Syringes	**Sterile Insulin Syringe for Single use, with needle**
Manufacturer		CHIRANA T. Injecta	Shanghai Kohope Medical Devices Co., Ltd
510(k) Number		Subject	K190002
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[1]	27G, 29G, 30G, 31G	29G, 30G, 31G
	Length[2]	6mm, 8mm, 12.7mm	8mm, 13mm

		CHIRANA® Insulin Syringes	Sterile Insulin Syringe for Single use, with needle
Materials	Needle	Stainless Steel 304	Stainless Steel 304
	Barrel	Polypropylene	Polypropylene
	Plunger	Polypropylene	Polypropylene
	Hub Tip[3]	Polystyrene	Isoprene rubber
	Needle Cap	Polyethylene	Polypropylene
	Protective End Cap	Polyethylene	Polypropylene
	Cannula Lubricant[3]	Medical Grade Silicone	Unknown
Biocompatibility		Conforming to ISO 10993-1	Conforming to ISO 10993-1
Sterilization[4]		EO (ethylene gas) to SAL=10^{-6}	SAL=10^{-6}

[1]The subject offers additional needle gauges than the predicate to accommodate a wider range of patient needs. This difference does not affect the safety and effectiveness of the subject because all subject needle gauges are standard syringe needle gauges.
[2]The subject offers additional needle lengths than the predicate to accommodate a wider range of patient needs. This difference does not affect the safety and effectiveness of the subject because all subject needle lengths are standard syring needle lengths.
[3]The subject hub tip and cannula lubricant materials are similar but not identical to that of the predicate components. Biocompatibility testing and performance testing confirmed that all materials of subject are safe and effective for use.
[4]The subject and predicate are provided sterile to the SAL of 10^{-6}. The sterilization method of the predicate is not publically known, but this does not introduce any questions for safety and effectiveness because the subject sterilization method has been validated per ISO 11135.

Performance Testing

The sterile CHIRANA® Insulin Syringes described in this summary were tested and demonstrated to be in conformance with the following FDA recognized standards:

- 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 methods

Biocompatibility

In accordance with ISO 10993-1, the needle is classified as: Externally Communicating Device, Blood Path Indirect, Prolonged Contact (24 hours to 30 days). The following testing was conducted:

- Cytotoxicity
- Sensitization
- Irritation and Intracutaneous Reactivity
- Subacute/Sub-chronic Toxicity
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity
- Hemocompatibility

Particulate matter testing was conducted in accordance with USP <788> Particulate Matter in Injections and met the USP acceptance criteria.

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
- Package integrity testing, after environmental conditioning and simulated transportation in accordance with ASTM D4169-16: Standard Practice for Performance Testing of Shipping Containers and Systems was conducted on the final, packaged, and sterile devices
- 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
- Shelf life of 2 years and four months for multi-unit packaging is validated with closure integrity test

Conclusions

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The CHIRANA® Insulin Syringes are substantially equivalent to the Syringe for Single use, with needle (K190002) with respect to the indications for use, target populations, treatment method, and technological characteristics.