Chirana T. Injecta
% Nathan Wright
Engineer and Regulatory Specialist
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K220614
Trade/Device Name: MEDOJECT fine Pen Needles
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: May 11, 2022
Received: May 13, 2022

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,

Courtney Evans -S

Digitally signed by Courtney Evans -S
Date: 2022.06.15 15:32:31 -04'00'

For 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)*
K220614

Device Name
MEDOJECT™ fine Pen Needles

Indications for Use *(Describe)*
MEDOJECT™ fine Pen Needles for single use are intended for subcutaneous delivery of insulin in conjunction with injection pens.

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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K220614 - 510(K) SUMMARY

Preparation Date:	March 2, 2022
Submitter's Name:	CHIRANA T. Injecta, a.s.
Submitter's Address:	Nám. Dr. Schweitzera 194 Stará Turá 916 01 Slovak Republic
Submitter's Telephone:	421-32-770-9972
Contact Person:	Nathan Wright MS Empirical Testing Corp. 1-719-351-0248 nwright@empiricaltech.com
Trade or Proprietary Name:	MEDOJECT™ *fine* Pen Needles
Classification Name:	Hypodermic single lumen needles
Classification:	Class II per 21 CFR §880.5570
Product Code:	FMI
Classification Panel:	Drug Delivery and General Hospital Devices, and Human Factors (DHT3C)

Predicate Device: K213407, UltiCare Disposable Pen Needles, UltiMed Incorporated

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The MEDOJECT™ *fine* Pen Needles consist of a cap, needle cap, needle, hub, and paper. The cap and paper function to maintain the sterility of the needle. The device is single use and supplied sterile (ethylene oxide sterilized). The hub is connected to the injection pen for manual subcutaneous injection of appropriate does to the user. The needle cap protects the needle. The available size options are shown below.

Needle Size	Color Code	Item Code
29G x 10mm	Yellow	CHPN2910
29G x 12.7mm	Pink	CHPN29127
30G x 6mm	Dark Blue	CHPN3006
30G x 8mm	Light Blue	CHPN3008
31G x 4mm	Green	CHPN3104
31G x 5mm	Dark Violet	CHPN3105

Needle Size	Color Code	Item Code
31G x 6mm	Dark Blue	CHPN3106
31G x 8mm	Light Blue	CHPN3108
32G x 4mm	Green	CHPN3204
32G x 5mm	Dark Violet	CHPN3205
32G x 6mm	Dark Blue	CHPN3206
32G x 8mm	Light Blue	CHPN3208

INDICATIONS FOR USE

The MEDOJECT™ *fine* Pen Needles are single use and are intended for subcutaneous delivery of insulin in conjunction with injection pens.

Characteristic	**Subject Device** MEDOJECT™ *fine* Pen Needles	**Predicate Device** UltiCare Disposable Pen Needles, UltiMed Incorporated (K213407)
Indications for Use	MEDOJECT™ *fine* Pen Needles for single use are intended for subcutaneous delivery of insulin in conjunction with injection pens.	The UltiCare™ Disposable Pen Needles are used with pen injector devices for the subcutaneous injection of drugs.
Rx or OTC	Over the Counter	Over the Counter

Discussion of differences in Indications for Use:

There are editorial differences to the indications for use statement between the subject and predicate device which do not change the indications. The predicate generically indicates the pen needles for drug delivery while the subject limits the delivery to only insulin, which is within the predicate indication.

TECHNOLOGICAL CHARACTERISTICS

The table below includes a comparison of the technological characteristics between the subject and the predicate devices:

	MEDOJECT™ *fine* Pen Needles	**UltiCare Disposable Pen Needles**	**Comparison**
510(k) Number	Subject	K213407	
Manufacturer	CHIRANA T. Injecta, a.s.	UltiMed Incorporated	
Regulation Number	21 CFR § 880.5570	21 CFR § 880.5570	Same
Classification Name	Hypodermic Single Lumen Needle	Hypodermic Single Lumen Needle	Same
Regulatory Class	Class II	Class II	Same
Product Code	FMI	FMI	Same
Operating Principle	The user manually inserts the needle tip into the skin to deliver insulin to the patient through a pen injector to which the pen needle is attached.	The user manually inserts the needle tip into the skin to deliver drug to the patient through a pen injector to which the pen needle is attached.	Same
Needle Gauge	29G, 30G, 31G, 32G	29G, 30G, 31G, 32G	Same
Needle Length[1]	4mm, 5mm, 6mm, 8mm, 10mm, 12.7mm	4mm, 5mm, 6mm, 8mm, 12.7mm	Similar
Material[2]	Cannula: 304 stainless steel Needle hub: polypropylene Needle Outer Cap: polypropylene Needle Inner Cap: polyethylene Joint medium: Medical grade glue Lubricant: medical grade silicone Seal: medical paper	Cannula: 304 stainless steel Needle hub: polyethylene Needle Outer Cap: Unknown Needle Inner Cap: Unknown Joint medium: Unknown Lubricant: Unknown Seal: Unknown	See Note
Needle Connector Type	Compatible with pen injectors which comply to ISO 11608-1 with screw threading attachment.	Compatible with pen injectors which comply to ISO 11608-1 with screw threading attachment.	Same
Design[3]	Outer Cap; Inner Cap; Cannula; Hub; Paper Seal 	Protective Outer Container; Shield; Cannula; Hub 	Similar
Biocompatibility	Per ISO 10993	Per ISO 10993	Same
Sterility	Ethylene Oxide to SAL of 10^{-6}	Ethylene Oxide to SAL of 10^{-6}	Same
Shelf Life[4]	5 years	Unknown	See Note

[1]The subject offers an additional needle length (10mm) not offered by 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 according to the size specifications in ISO 11608-2.

[2]Subject and predicate materials are similar but not identical. Differences in hub materials or in joint medium, lubricant, and seal do not introduce concerns for safety and efficacy of the subject device. Biocompatibility testing and performance testing confirmed that all materials of subject are safe and effective for use.

[3]The subject and predicate have the same needle, hub, and outer and inner cap design. The use of a paper seal and its material in the predicate is unknown. Differences in paper seal do not affect safety and effectiveness of the subject device. Performance testing confirmed that the subject design was safe and effective for use.

[4]Differences in shelf life would have no effect on the safety and effectiveness of the subject device. The shelf life of the sterile subject device was established through shelf life testing.

PERFORMANCE DATA

The MEDOJECT™ *fine* Pen Needles described in this summary were tested and demonstrated to be in conformance with the following FDA recognized standards:

- ISO 7864 4th Ed-2016, Sterile hypodermic needles for single use – Requirements and test methods
  - Limits for extractable metals

- ISO 11608-2 2nd Ed-2012, Needle-based injection systems for medical use – Requirements and test methods – Part 2: Needles
    - Flow rate through rate
    - Bond between hub and needle tube
    - Functional compatibility with insulin injectors
    - Ease of assembly and disassembly
- ISO 9626 2nd Ed-2016, Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods
    - Needle sharpness – penetration force
    - Limits of acidity and alkalinity
    - Stiffness
    - Resistance to breakage
    - Resistance to corrosion

Biocompatibility

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

- Cytotoxicity (ISO 10993-5)
- Sensitization (ISO 10993-10)
- Irritation/Intracutaneous reactivity (SIO 10993-10)
- Subacute/Sub-chronic Toxicity (ISO 10993-11)
- Acute Systemic Toxicity (ISO 10993-11)
- Material-Mediated Pyrogenicity (ISO 10993-11/USP <151>)
- Hemocompatibility (ASTM F756)

Sterility, Shipping, and Shelf-Life

- EO sterilization validation (ISO 11135)
- Simulated Packaging (ASTM D4169)
- Accelerated aging for shelf-life (ASTM F1980)

CONCLUSION

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The MEDOJECT™ *fine* Pen Needles are substantially equivalent to the UltiCare Disposable Pen Needle (K213407) with respect to the indications for use, target populations, treatment method, and technological characteristics.