June 21, 2023

Cardinal Health 200, LLC
Emily Hunter
Senior Specialist, Regulatory Affairs
3651 Birchwood Drive
Waukegan, Illinois 60085

Re: K223376
Trade/Device Name: Monoject Magellan Insulin Safety Syringe 1mL, 31G x 6mm (8881893110);
Monoject Magellan Insulin Safety Syringe 0.5mL, 31G x 6mm (8881893150);
Monoject Magellan Insulin Safety Syringe 0.3mL, 31G x 6mm (8881893130)
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: MEG, FMF, FMI
Dated: May 24, 2023
Received: May 25, 2023

Dear Emily Hunter:

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 M. 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)*
K223376

Device Name
Monoject Magellan Insulin Safety Syringe 1 ml, 31 G x 6mm (888189311 0);
Monoject Magellan Insulin Safety Syringe 0.5ml, 31G x 6mm (8881893150);
Monoject Magellan Insulin Safety Syringe 0.3ml, 31G x 6mm (8881893130)

Indications for Use *(Describe)*
Monoject Magellan Insulin Safety Syringes are intended for delivery of U-100 insulin. The needle stick prevention feature of the device, once activated, guards against accidental needle-sticks.

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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K223376 510(k) Summary

Submitter Information:

Cardinal Health 200, LLC
3651 Birchwood Drive
Waukegan, IL 60085, USA

Contact Person: Emily Hunter
Phone: 847-887-6367
Email: emily.hunter01@cardinalhealth.com

Date of Preparation: June 20, 2023

Device

TRADE NAME	Monoject™ Magellan™ Insulin Safety Syringe
COMMON NAME	Insulin Syringe, with sharps injury prevention feature
CLASSIFICATION NAME	Piston Syringe
REGULATION NUMBER	21 CFR 880.5860
REGULATORY CLASS	II
PRODUCT CODES	MEG, FMF, FMI
CLASSIFICATION PANEL	General Hospital

Predicate Device

510(k) Number: K061492
Device Name: Monoject™ Magellan™ Insulin Safety Syringe

Device Description

The Monoject™ Magellan™ Insulin Safety Syringe consists of a piston syringe with a permanently attached needle, and safety shield designed to extend, fully cover, and permanently lock over the needle when activated by a fingertip or thumb to reduce the occurrence of accidental needle sticks. The device is provided sterile and is intended for single use only. An orange needle cap indicates for use with insulin. The barrel of the syringe is graduated for measuring a prescribed dose. The syringe is intended for use immediately after filling and is not intended to contain or store insulin for extended periods of time.

A complete list of the subject devices proposed model numbers is included in Table 1

Table 1: Proposed Subject device model numbers

Product Code	Product Description
8881893130	Monoject Magellan Insulin Safety Syringe, 0.3mL, 31G x 6mm needle
8881893150	Monoject Magellan Insulin Safety Syringe, 0.5mL, 31G x 6mm needle
8881893110	Monoject Magellan Insulin Safety Syringe, 1.0mL, 31G x 6mm needle

Indications for Use

Monoject Magellan Insulin Safety Syringes are intended for delivery of U-100 insulin. The needle stick prevention feature of the device, once activated, guards against accidental needle-sticks.

Comparison of Technological Characteristics with the Predicate Device

Subject Monoject Magellan Insulin Safety Syringe has similar materials, and identical design, components, technological characteristics, intended use, and indications for use as the predicate device. Biocompatibility evaluation and testing in conformance with ISO 10993 series standards was completed to verify similar materials. Differences exist in needle gauge, length, and wall thickness; needle of subject device is smaller, shorter, and thinner than needle of predicate. Differences have been verified in conformance with FDA recognized standard ISO 8537:2016 *Sterile single-use syringes, with or without needle, for insulin.*

Table 2: Comparison of Technological Characteristics of Subject Device with Predicate Device

Description	Subject Device Monoject Magellan Insulin Safety Syringe K223376	Predicate Device Kendall Monoject Magellan Insulin Safety Syringe K061492	Comparison
Indications for use	Monoject Magellan Insulin Safety Syringes are intended for delivery of U-100 insulin. The needle stick prevention feature of the device, once activated, guards against accidental needle-sticks.	The device is intended for the delivery of U-100 insulin. The needle stick prevention feature of the device, once activated, guards against accidental needle-sticks.	Same
Intended Use	Primarily intended for intra-muscular, subcutaneous, and/or intra-dermal medication delivery. Secondary use is a safety feature that helps prevent sharps injuries.	Primarily intended for intra-muscular, subcutaneous, and/or intra-dermal medication delivery. Secondary use is a safety feature that helps prevent sharps injuries.	Same
Syringe Type	Piston Syringe	Piston Syringe	Same
Principle of Operation	Manually extendable safety shield, one handed activation	Manually extendable safety shield, one handed activation	Same
Specific Drug Use	Insulin	Insulin	Same
Needle size	31G	29G, 30G	Different
Needle length	6mm (15/64”)	8mm (5/16”) 13mm (1/2”)	Different
Wall thickness	Extra thin wall	Regular Wall	Different
Needle bevel	Conforms to ISO 7864	Conforms to ISO 7864	Same
Needle Sheath Color	Orange	Orange	Same
Needle Lubricant	Silicone	Silicone	Same
Needle Material	Type 304 Stainless Steel	Type 304 Stainless Steel	Same
Syringe volumes	0.3mL 0.5mL 1.0mL	0.3mL 0.5mL 1.0mL	Same
Barrel Lubricant	Silicone	Silicone	Same

Description	Subject Device Monoject Magellan Insulin Safety Syringe K223376	Predicate Device Kendall Monoject Magellan Insulin Safety Syringe K061492	Comparison
Barrel Materials	Polypropylene	Polypropylene	Similar
Barrel Nozzle	Fixed Needle	Fixed Needle	Same
Barrel Transparency	Clear	Clear	Same
Safety Shield Material	Polyethylene	Polyethylene	Same
Sterilization Method	Gamma Radiation	Gamma Radiation	Same
SAL	10^{-6}	10^{-6}	Same
Reuse Durability	Single use only	Single use only	Same
Delivery Accuracy	Conforms to ISO 8537	Conforms to ISO 8537	Same
Hub/Needle Bond Strength	Conforms to ISO 8537	Conforms to ISO 8537	Same
Biocompatibility	Conforms to ISO 10993-1	Conforms to ISO 10993-1	Same

Biocompatibility

Biocompatibility evaluation was conducted considering worst-case, clinical use, and potential repeat contact in conformance with ISO 10993-1:2018 *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process* and FDA Guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"*. Applicable testing was completed utilizing the ISO 10993 series standards following Good Laboratory Practices. Monoject™ Magellan™ Insulin Safety Syringes with permanently attached 31G x 6mm needle are concluded to be toxicologically acceptable for the intended use.

Sterility

Monoject™ Magellan™ Insulin Safety Syringes with permanently attached 31G x 6mm needle is sterilized using gamma irradiation to a sterility assurance level of 10^{-6}. Devices are nonpyrogenic as determined by the *Limulus* Amebocyte Lysate (LAL) Test. Validation and testing was completed following FDA Guidance *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile*, ISO 11137-2:2013 *Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose*, ANSI AAMI ST72:2019 *Bacterial Endotoxins – Test methods, routine monitoring, and alternatives to batch testing*, and USP Chapter <85>, *Bacterial Endotoxins Test.*

Performance Data

Nonclinical tests

Monoject™ Magellan™ Insulin Safety Syringes with permanently attached 31G x 6mm needle underwent evaluation following FDA Guidance documents and FDA recognized standards to support substantial equivalence determination:

- Guidance on the Content of Premarket Notification [510(K)] Submissions for Piston Syringes

- ISO 8537:2016 *Sterile single-use syringes with or without needle for insulin*
- ISO 10993-1:2018 *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*
- ISO 11607-1:2019 *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems*
- ISO 11607-2:2019 *Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes*
- USP <788> Particulate Testing

Conclusion

Results of non-clinical testing support the conclusion that Monoject™ Magellan™ Insulin Safety Syringes with permanently attached 31G x 6mm needle are as safe, as effective, and performs as well as the predicate device, therefore subject device is substantially equivalent to the predicate device.