July 13, 2026

embecta Medical II, LLC
Ewelina Rog
Senior Manager, Regulatory Affairs
300 Kimball Dr.
Parsippany, New Jersey 07054

Re: K260208
Trade/Device Name: Ultra-Fine™ SAFETY Insulin Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, MEG
Dated: June 16, 2026
Received: June 16, 2026

Dear Ewelina Rog:

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, M.S.
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

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.	K260208

Please provide the device trade name(s).

Ultra-Fine™ SAFETY Insulin Syringe

Please provide your Indications for Use below.

Ultra-Fine SAFETY Insulin Syringes are intended to be used for subcutaneous administration of insulin for the treatment of diabetes mellitus at a concentration of 100U/mL (U-100), while reducing the occurrence of accidental needle sticks during normal handling and disposal of the used needle/syringe combination.

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

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

510(k) Summary

Submitter	embecta Medical II LLC 300 Kimball Drive Parsippany, NJ 07054
Contact Person	Ewelina Rog Senior Manager, Regulatory Affairs Phone: (734) 433-8817
Date Prepared	July 10, 2026
Trade Name	Ultra-Fine™ SAFETY Insulin Syringe
Common Name	Piston Syringe
Device Class	II
Regulation Number	21 CFR 880.5860
Classification Panel	80; General Hospital
Product Code	FMF (Syringe, Piston) MEG (Syringe, Antistick)

Predicate Device
Legally marketed predicate device to which substantial equivalence is being claimed:
K190054 – BD Insulin Syringe

Device Description
The Ultra-Fine SAFETY Insulin Syringe is a single-use, plastic, sterile, non-pyrogenic device designed for subcutaneous administration of 100U/mL (U-100) insulin. The Ultra-Fine SAFETY Insulin Syringe device assembly consists of a needle shield, needle (cannula), barrel with graduated scale, plunger rod with a plunger stopper, and a safety mechanism. When activated, the safety mechanism covers the needle (cannula) and guards against accidental needle sticks during normal handling and disposal of the used device. The device operates on the principles of a piston syringe.

Indications For Use
Ultra-Fine SAFETY Insulin Syringes are intended to be used for subcutaneous administration of insulin for the treatment of diabetes mellitus at a concentration of 100U/mL (U-100), while reducing the occurrence of accidental needle sticks during normal handling and disposal of the used needle/syringe combination.

Summary of Technological Characteristics
The technological characteristics of the subject Ultra-Fine SAFETY Insulin Syringe are similar to the predicate BD Insulin Syringe. A comparison between Ultra-Fine SAFETY Insulin Syringe

(subject device) and BD Insulin Syringe (predicate device), cleared under K190054, is outlined in Table 1 below.

Table 1. Comparison of Technological Characteristics with the Predicate Device

General Information Feature	Subject Device (Ultra-Fine SAFETY Insulin Syringe)	Predicate Device (BD Insulin Syringe) K190054	Comparison
General Information			
Device Class	II	II	**Same**
Regulation Number	21 CFR 880.5860	21 CFR 880.5860	**Same**
Product Code	FMF (Syringe, Piston) MEG (Syringe, Antistick)	FMF (Syringe, Piston)	Different – FDA product code MEG was included to support the subject device's antistick claim. Although the device may be classified under two product codes, both are governed by the same FDA regulation number (21 CFR 880.5860); therefore, this difference does not impact the determination of substantial equivalence.
Specific Drug Use	U-100 Insulin	U-100 Insulin	**Same**
Indications for Use	Ultra-Fine SAFETY Insulin Syringes are intended to be used for subcutaneous administration of insulin for the treatment of diabetes mellitus at a concentration of 100U/mL (U-100), while reducing the occurrence of accidental needle sticks during normal handling and disposal of the used needle/syringe combination.	Insulin syringes are intended for subcutaneous injection of U-100 insulins.	**Same** – Both the predicate and subject devices are intended for subcutaneous injection of insulin. The subject device includes an additional statement to describe the presence of the safety mechanism, but this feature does not alter the overall intended use.
Single Use Only	Yes	Yes	**Same**
Volumetric Capacity	0.3 mL, 0.5 mL, 1 mL	0.3 mL, 0.5 mL, 1 mL	**Same**
Needle (Cannula) Gauge Size	29G, 30G, 31G	27G, 28G, 29G, 30G, 31G	Different – Predicate device has an additional 27G and 28G configuration.
Needle (Cannula) Length Size	6mm, 8mm, 12.7mm	6mm, 8mm, 12.7mm, 16mm	Different – Predicate device has an additional 16mm configuration.

Table 1. Comparison of Technological Characteristics with the Predicate Device

General Information Feature	Subject Device (Ultra-Fine SAFETY Insulin Syringe)	Predicate Device (BD Insulin Syringe) K190054	Comparison
Nozzle Tip Type	Permanently attached needle	Permanently attached needle	**Same**
Mechanism of Connection – Hub	0.3 mL: Snap-Fit 0.5 mL: Snap-Fit 1 mL: Snap-Fit	0.3 mL: Snap-Fit 0.5 mL: Snap-Fit 1 mL: Integral	Different – Verification testing conducted on the subject device confirmed the snap-fit meets all applicable requirements and functions as intended in accordance with ISO 8537. The differences between the 1 mL configurations do not raise different questions of safety and effectiveness.
Graduated Scale – Unit Increments	0.3 mL: ½-unit or 1-unit 0.5 mL: 1-unit 1 mL: 1-unit	0.3 mL: ½-unit or 1-unit 0.5 mL: 1-unit 1 mL: 2-unit	Different – Verification testing conducted on the subject device confirmed the graduated scale unit increments meet all applicable requirements and function as intended in accordance with ISO 8537. The differences between the 1 mL configurations do not raise different questions of safety and effectiveness.
Safety Mechanism	Yes	No	Different – Specific to the safety mechanism of the subject device. *See comment #1*
Non-Pyrogenic	Yes	Yes	**Same**
Sterilization Method	Gamma Irradiation	Gamma Irradiation	**Same**
SAL 10^{-6}	Yes	Yes	**Same**
Packaging Configuration	Blister Package	Blister Package Self-Contained Polybag	**Same** – Predicate device has an additional self-contained polybag configuration.
Shelf-Life	5 years	5 years	**Same**
Materials			
Needle (Cannula)	304 Stainless Steel	304 Stainless Steel	**Same**

Table 1. Comparison of Technological Characteristics with the Predicate Device

General Information Feature	Subject Device (Ultra-Fine SAFETY Insulin Syringe)	Predicate Device (BD Insulin Syringe) K190054	Comparison
Needle Shield	Polypropylene	Polyethylene	Different – The subject needle shield features a relief cutout to accommodate the safety mechanism. *See comment #2*
Needle Shield Color	Orange Colorant	Orange Colorant	Different – While the shield color is unchanged, the underlying color formulation differs. *See comment #2*
Cannula Lubricant	Silicone Fluid	Silicone Fluid	**Same**
Adhesive	UV Cured Adhesive	UV Cured Adhesive	**Same**
Graduated Scale	Solvent Based Markem Black Colored Ink	Solvent Based Markem Black Colored Ink	**Same**
Plunger Rod	Polystyrene	Polystyrene	**Same**
Plunger Stopper	Rubber Stopper	Rubber Stopper	**Same**
Plunger Stopper Lubricant	Medical Grade Silicone	Medical Grade Silicone	**Same**
Barrel	Polypropylene	Polypropylene	**Same**
Barrel Lubricant	Medical Grade Silicone	Medical Grade Silicone	**Same**
Snap-Fit Hub	Polypropylene	Polypropylene	**Same**
Pushrod	Polycarbonate White Colorant	N/A – Specific to the safety mechanism of the subject device.	Different – For the subject device, the safety mechanism is comprised of the pushrod and adapter, which is not present in the predicate device. *See comment #2*
Adapter	Polycarbonate	N/A – Specific to the safety mechanism of the subject device.	
Performance			
Syringe Performance	ISO 8537	ISO 8537	**Same**
Needle (Cannula) Performance	ISO 8537 ISO 9626 ISO 7864	ISO 8537 ISO 9626 ISO 7864	**Same**

Table 1. Comparison of Technological Characteristics with the Predicate Device

General Information Feature	Subject Device (Ultra-Fine SAFETY Insulin Syringe)	Predicate Device (BD Insulin Syringe) K190054	Comparison
Safety Performance	ISO 23908	N/A – Specific to the safety mechanism of the subject device.	Different – Specific to the safety mechanism of the subject device. Design verification per ISO 23908 confirmed the safety mechanism meets all applicable requirements and functions as intended, supporting a determination of substantial equivalence.

Discussion of differences in technological characteristics:

- ***Comment #1:*** Design verification per ISO 23908, the sharps injury prevention simulated use study, and the human factors summative validation study demonstrated that the safety mechanism performs as intended and can be used safely and effectively by the intended users. These results show that the addition of the safety mechanism does not raise different questions of safety and effectiveness compared to the predicate device.
- ***Comment #2:*** A biocompatibility evaluation was conducted in accordance with ISO 10993-1 and supports that the identified differences do not raise different questions of safety and effectiveness, supporting a determination of substantial equivalence.

Summary of Non-Clinical Performance Data

Performance testing was conducted per FDA recognized consensus standards and met all acceptance criteria. The results confirmed that the subject device is substantially equivalent to the predicate device. The following performance data was provided in support of the substantial equivalence determination:

- ASTM D4169-22 - Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM F88/F88M-23 - Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F2096-11 - Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test) (Reapproved 2019)
- ISO 8537:2016 - Sterile single-use syringes, with or without needle, for insulin
- ISO 9626:2016 - Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
- ISO 7864:2016 - Sterile hypodermic needles for single use - Requirements and test methods
- ISO 23908:2024 - Sharps injury protection - Sharps protection mechanisms for single-use needles, introducers for catheters and needles used for blood testing, monitoring, sampling and medical substance administration - Requirements and test methods
- USP <161> - Medical Devices - Bacterial Endotoxin and Pyrogen Tests

Biocompatibility Testing
A biocompatibility evaluation for the Ultra-Fine SAFETY Insulin Syringe was performed based on the requirements of ISO 10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process. The Ultra-Fine SAFETY Insulin Syringe is categorized as externally communicating with direct tissue contact and is used for a prolonged duration (more than 24 hours but less than 30 days). The following biological endpoints were evaluated and used to demonstrate substantial equivalence:

- Cytotoxicity
- Irritation Intracutaneous Reactivity
- Sensitization
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Genotoxicity
- Subacute Toxicity (Systemic Toxicity)

Sterilization
The Ultra-Fine SAFETY Insulin Syringe is sterilized by gamma irradiation. The sterilization process has been validated in accordance with ISO 11137-1:2025, Sterilization of health care products - Radiation - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices, ISO 11137-2:2013[AMD1:2022], Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose, and ANSI AAMI ISO 13004:2022, Sterilization of health care products - Radiation - Substantiation of selected sterilization dose: Method VDmaxSD. The sterilization parameters were chosen to assure the sterilization dose provides a minimum Sterility Assurance Level (SAL) of 10^{-6}.

Sharps Injury Prevention Simulated Use
In accordance with FDA guidance document, *Medical Devices with Sharps Injury Prevention Features*, a sharps injury prevention simulated use study was conducted using the Ultra-Fine SAFETY Insulin Syringe to evaluate the sharps injury prevention (SIP) feature. This study concluded with zero failures observed and was considered successful according to the criteria outlined within the FDA guidance.

Summary of Clinical Testing
Not applicable.

Conclusion
The differences between the predicate and the subject device do not raise different questions of safety or effectiveness. The information submitted within this Traditional 510(k) demonstrates the Ultra-Fine SAFETY Insulin Syringe is substantially equivalent to the predicate BD Insulin Syringe.