510(K) SUMMARY
(K180720)

1. 510k Submitter

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MEDIBIO USA LLC.
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2. US Agent/Contact Person:

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3. Device Name:

- Trade Name : Medifine Pen Needle 3 Bevel
  Medifine Pen Needle Quinta 5 Bevel
- Classification : Class II
- Regulation Description : Hypodermic single lumen needle
- Product Code : FMI
- Regulation Number : 21 CFR 880.5570
- Review Panel : General Hospital

3. Predicate Device:

- Predicate Device: Medifine Pen Needle 3 Bevel & Medifine Pen Needle Quinta 5 Bevel (K171144) by MEDIBIO USA LLC.
- Secondary Predicate Device: CareFine Pen Needle by Facet Technologies, LLC (K140568)

4. Device Description:

The Medifine Pen Needle consists of a needle with hub, and shield assembly. The needle shield is intended to provide physical protection to the needle with the hub. Blister paper covers the primary container. The primary container maintains sterility of the needle covering the hub and the shield with the blister paper. The needle hub can be connected onto the pen injector device for the subcutaneous injection of insulin.
The device offers two compatible types of needle (patient contact point) as below. The user can choose the needle as per their preference.

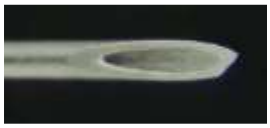
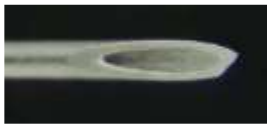
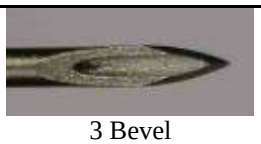
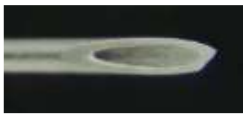
5. Indications For Use:

The Medifine Pen Needle 3 Bevel and the Medifine Pen Needle Quinta 5 Bevel are indicated for use with a pen injector device for the subcutaneous injection of insulin.

6. Technological Characteristics:

The Medifine Pen Needle 3 Bevel and Medifine Pen Needle Quinta 5 Bevel is substantially equivalent to the K171144. There is no modification to the device since the 510k clearance (K171144). The subject device and the predicate device are identical including manufacturing facility and manufacturing processes. This 510k is to include OTC claim since the predicate device only has the prescription claim. The secondary predicate device is presented for the OTC claim.

	Subject Device	**Predicate Device**	**Secondary Predicate Device**
Device Name	Medifine Pen Needle 3 Bevel Medifine Pen Needle Quinta 5 Bevel	Medifine Pen Needle 3 Bevel Medifine Pen Needle Quinta 5 Bevel	CareFine Pen Needle
Manufacturer	TAE-CHANG INDUSTRIAL CO.,LTD	TAE-CHANG INDUSTRIAL CO.,LTD	TAE-CHANG INDUSTRIAL CO.,LTD
510k Applicant	MEDIBIO USA LLC.	MEDIBIO USA LLC.	Facet Technologies, LLC
Product Code	FMI	FMI	FMI
510k Number	K180720	K171144	K140568
Indications for use	The Medifine Pen Needle 3 Bevel and the Medifine Pen Needle Quinta 5 Bevel are indicated for use with a pen injector device for the subcutaneous injection of insulin.	The Medifine Pen Needle 3 Bevel and the Medifine Pen Needle Quinta 5 Bevel are indicated for use with a pen injector device for the subcutaneous injection of insulin.	The CareFinePen Needle is intended for use with a pen injector device for the subcutaneous injection of insulin.
Structure	Cannula / Hub / Needle Cap / Primary Container	Cannula / Hub / Needle Cap / Primary Container	Cannula / Hub / Needle Cap / Primary Container
Principle of Operation	Pen needle is indicated for use with pen injector devices for the subcutaneous injection of insulin.	Pen needle is indicated for use with pen injector devices for the subcutaneous injection of insulin.	Pen needle is intended for use with pen injector devices for the subcutaneous injection of insulin.
Shape			
Needle Diameter	29G, 30G, 31G, 32G	29G, 30G, 31G, 32G	29G, 30G, 31G, 32G
Needle Tube Length	4mm, 5mm, 6mm, 8mm, 12.7mm	4mm, 5mm, 6mm, 8mm, 12.7mm	4mm, 5mm, 6mm, 8mm, 12.7mm
Needle Tube Material	Stainless steel	Stainless steel	Stainless steel
Needle Hub Material	Polypropylene	Polypropylene	Polypropylene
Needle shield Material	Polyethylene	Polyethylene	Polyethylene
Primary container Material	Polypropylene	Polypropylene	Polypropylene

Tip Configuration (Patient Side)	 3 Bevel  5 Bevel	 3 Bevel  5 Bevel	 3 Bevel  5 Bevel
Primary Container Length	29.93mm	29.93mm	29.93 [mm]
Primary Container Color	Transparent	Transparent	Transparent
Primary Container Removal Force	220~1100 [gf]	220~1100 [gf]	220~1100 [gf]
Needle Hub/needle Tube bond Strength	Min. 22 [N]	Min. 22 [N]	Min. 22 [N]
Lubricant Composition	**Patient-end point:** Dow Conrning®Mdx4-4159 50% Medical Grade **Cartridge-end point :** Dow Corning®360 Medical Fluid, 100CST	**Patient-end point:** Dow Conrning®Mdx4-4159 50% Medical Grade **Cartridge-end point :** Dow Corning®360 Medical Fluid, 100CST	**Patient-end point:** Dow Conrning®Mdx4-4159 50% Medical Grade **Cartridge-end point :** Dow Corning®360 Medical Fluid, 100CST
Sterilization method	EO Gas	EO Gas	EO Gas
Prescription /Over-the-Counter	Prescription /Over-the-Counter	Prescription	Over-the-Counter

7. Performance Testing

The following tests were performed on the Medifine Pen Needle 3 Bevel and Medifine Pen Needle Quinta 5 Bevel and the test results show that the subject device is substantially equivalent to the predicate devices in the market.

No	Test item	Test Method
1	Dimensions	ISO 11608-2:2012 Clause 4.2.1General ISO 9626 1991_Amd2001, clause8
2	Dimensions for needles	ISO 11608-2:2012 Clause 4.2.2 Dimensions for needles
3	Determination of flow rate through the needle	ISO 11608-2:2012 Clause 4.3 Determination of flow rate through the needle
4	Bond between hub and needle tube	ISO 11608-2:2012 Clause 4.4 Bond between hub and needle tube ISO 7864 Clause 13.1
5	Needle points	ISO 11608-2:2012 Clause 4.5 Needle point
6	Freedom from defects	ISO 11608-2:2012 Clause 4.6 Freedom from defects ISO 7864 Clause 11.3
7	Lubrication	ISO 11608-2:2012 Clause 4.7 Lubrication

8	Dislocation of measuring point at patient end	ISO 11608-2:2012 Clause 4.8 Dislocation of measuring point at patient end
9	Determination of functional compatibility with needle-based injection systems	ISO 11608-2:2012 Clause 4.9 Test Method - Clause 11.
10	Ease of assembly and disassembly	ISO 11608-2:2012 Clause 4.10 Test Method – Clause 11
11	Compatibility of Needles and Injector systems	ISO 11608-2:2012 Clause 11 Test Method – Clause 11
12	Cannula Test	ISO 9626 Clause 4,5,6,7,8,9,10,11
13	Extraction Test	ISO 7864 Clause 6
14	Corrosion Test	ISO 9626 Clause 11
15	Sterility Test	ISO 11737-2
16	Packaging/Aging Test	ASTM D4169-09, ISO 11608-2, ASTM F1929, ISO 11608-2
17	Biocompatibility	The raw material of the subject device as well as the manufacturing processes and sterilization method are the same as the predicate device (K171144).

8. Conclusion

Based on the information provided in this premarket notification, MEDIBIO USA LLC. concludes that the Medifine Pen Needle 3 Bevel and Medifine Pen Needle Quinta 5 Bevel are substantially equivalent to the predicate devices.