



Food and Drug Administration
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February 2, 2016

MedExel Co., Ltd.
c/o Mr. Peter Chung
President
Plus Global
300 Atwood Street
Pittsburgh, Pennsylvania 15213

Re: K152410
Trade/Device Name: Top Fine[®] Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: December 16, 2015
Received: December 31, 2015

Dear Mr. Chung:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Tina Kiang
-S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K152410

Device Name
Top Fine® Pen Needle

Indications for Use (Describe)
Top Fine® Pen Needle is intended for use with pen injector device for the subcutaneous injection of 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary (K152410)

[as required by 807.92(c)]

Applicant

Company : MedExel Co.,Ltd.

Address : 252, Geumgwangosan-ro, Geumgwang-myeon, Anseong-si, Gyeonggi-do, Korea

Tel : 82-31-677-8004

Fax : 82-31-677-8087

Prepared date : Dec. 15, 2015

Contact person : Peter Chung, 412-687-3976

Contact person address : 300, Atwood Street, Pittsburgh, PA, 15213, USA

Current date : Jan. 15, 2016

510(k) Number : K152410

Device Information

Trade name : Top Fine[®] Pen Needle

Common name : Hypodermic single lumen needle

Classification name : Needle, Hypodermic, Single Lumen

Product code : FMI

Regulation number : 880.5570

Class of device : Class II

Panel : General Hospital

Model codes : 13 model codes including Top Fine[®] Pen Needle 29GX12mm

Top Fine [®] Pen Needle 29G X 12mm, 12.7mm
Top Fine [®] Pen Needle 30G X 8mm
Top Fine [®] Pen Needle 31G X 5mm, 6mm, 8mm
Top Fine [®] Pen Needle 32G X 4mm, 5mm, 6mm
Top Fine [®] Pen Needle 33G X 4mm, 5mm
Top Fine [®] Pen Needle 34G X 4mm, 5mm

The legally marketed device to which we are claiming equivalence

K080904 Feel Fine Insulin Pen Needle

Device description

Top Fine[®] Pen Needles are single use, sterile, medical devices designed to be used in conjunction with pen injectors and pen cartridges. Pen needles are used by consumers, caregivers and health care professionals. They are offered in various gauge sizes (29G, 30G, 31G, 32G, 33G and 34G) and lengths (4mm, 5mm, 6mm, 8mm, 12mm, and 12.7mm). Top Fine[®] Pen Needles are sterile (EO gas sterilization), non-toxic and non-pyrogenic.

Top Fine[®] Pen Needle assembly consists of hub, needle, needle cap, sterile cap and sterile paper.

Indications for Use :

Top Fine[®] Pen Needle is intended for use with insulin pens for the subcutaneous injection of insulin.

Performance data:

Bench tests relating to the performance of the Top Fine® Pen Needles were conducted.

The principal device demonstrated equivalent performance to the predicate devices during bench testing.

Bench testing consisted of:

Inside and outside dimensions of needles	Test standard ISO 11608-2:2012 ISO 7864:1993
Size designation	
Elasticity of the needle tube	
The flexural rigidity	
Pull	
Lubricant	
Compatibility test	
Needle dose accuracy	
Needle hub torque removal	

COMPATIBLE Pens

PEN NAME			
BD Pen	InDuo	Novopen 3ml	Novopen Junior
FlexPen	InnoLet	Sanofi SoloStar	Sanofi Optiset
HumalogPen	Humulin Pen	Sanofi OptiPen	Owen Autopen

Predicate device comparison table

Manufacturer	MedExel Co.,Ltd.	Feel Tech	Remark																				
510(k) No.	K152410	K080904	N/A																				
Indication for use	Top Fine® Pen Needle is intended for use with insulin pens for the subcutaneous injection of insulin.	These disposable sterile insulin pen needles are intended for subcutaneous injection of insulin in the treatment of diabetes.	Similar																				
Product name	Hypodermic single lumen needle	Hypodermic single lumen needle	Same																				
Trade name	Top Fine® Pen Needle	Feel Fine Insulin Pen Needle	N/A																				
Model/type	13 model codes including Top Fine® Pen Needle 29GX12mm	Feel Fine Insulin Pen Needle-29 Feel Fine Insulin Pen Needle-30 Feel Fine Insulin Pen Needle-31	N/A																				
Appearance			Similar																				
Product configuration	Hub Needle cap Sterile cap Needle Sterile paper	Hub Needle cap Sterile cap Needle Sterile paper	Similar																				
Material	<table border="1"> <thead> <tr> <th>Part</th> <th>Material</th> </tr> </thead> <tbody> <tr> <td>Sterile cap</td> <td>Polypropylene Polyethylene</td> </tr> <tr> <td>Needle cap</td> <td>Polyethylene</td> </tr> <tr> <td>Needle</td> <td>Stainless steel 304</td> </tr> <tr> <td>Hub</td> <td>Polypropylene</td> </tr> </tbody> </table>	Part	Material	Sterile cap	Polypropylene Polyethylene	Needle cap	Polyethylene	Needle	Stainless steel 304	Hub	Polypropylene	<table border="1"> <thead> <tr> <th>Part</th> <th>Material</th> </tr> </thead> <tbody> <tr> <td>Sterile cap</td> <td>Polypropylene</td> </tr> <tr> <td>Needle cap</td> <td>Polypropylene</td> </tr> <tr> <td>Needle</td> <td>Stainless steel 304</td> </tr> <tr> <td>Hub</td> <td>Polypropylene</td> </tr> </tbody> </table>	Part	Material	Sterile cap	Polypropylene	Needle cap	Polypropylene	Needle	Stainless steel 304	Hub	Polypropylene	Same or Similar
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Sterile cap	Polypropylene																						
Needle cap	Polypropylene																						
Needle	Stainless steel 304																						
Hub	Polypropylene																						
Length of parts (mm)																							
Total length of assembly	29.8	28.8	Similar																				
Side length of	15.2	15.5																					

Manufacturer	MedExel Co.,Ltd.	Feel Tech	Remark
assembly(max)			
Inner diameter of sterile cap	11.2	12.95	Similar
Gauge	29G, 30G, 31G, 32G, 33G, 34G	29, 30, 31G	Similar
Length of needle	4 mm, 5 mm, 6 mm, 8 mm, 12 mm, 12.7 mm	5 mm, 8 mm, 12.7 mm	Similar
Sterilization	EO Gas sterilization According to ISO 11135: 2007	EO Gas sterilization	Same
Packaging	Sterile cap(PP or PE)+sterile paper	Sterile cap(PP)+sterile paper	Similar

The bench tests of Needles with 32G, 33G, 34G demonstrated conformance to ISO 11608-2 and ISO 7864. Therefore the differences do not raise new concerns to establish substantial equivalence to the predicate.

Endotoxin Test was based on USP 39: <85> Bacterial Endotoxin test and KP 11: <32> Endotoxin Test Method.

Conclusion:

The vast similarities of the Top Fine® Pen Needle to the predicate devices support the substantial equivalence in indications for use, function and basic composition.

The differences between the Top Fine® Pen Needle and the predicate device do not raise new issues.

The testing that conformance with ISO 11608-2 and ISO 7864 provides additional evidence that the Top Fine® Pen Needle is substantially equivalent to the predicate device in terms of efficacy and performance.