DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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June 24, 2016

Owen Mumford Ltd
℅ Ms. Patty Cronan
Owen Mumford USA, Inc.
1755 West Oak Commons Court
Marietta, Georgia 30062

Re: K152339
Trade/Device Name: Unifine® Pentips® and Unifine® Pentips® Plus
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: June 17, 2016
Received: June 20, 2016

Dear Ms. Cronan:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152339

Device Name
Unifine Pentips/ Unifine Pentips Plus

Indications for Use *(Describe)*
The Unifine Pentips range of pen needles are intended for use with pen injector devices for the subcutaneous injection of drugs, including 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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SECTION 5.0

510(k) SUMMARY: 510k Number: K152339

1. Submitter

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Date Prepared: October 16, 2015

2. Device

Name of Device: Unifine® Pentips® & Unifine® Pentips® Plus
Common Name: Pen Needles
Classification Name: Needle, Hypodermic, Single Lumen (21 CFR 880.5570)
Regulatory Class: II
Product Code: FMI

3. Predicate Devices

Primary Predicate Device 1 Name: Unifine® Pentips®, K973899

Reference Predicate Device 2 Name: Artsana InsuPen® Insulin Pen Needles, K051783

Reference Predicate Device 3 Name: BD Pen Needles, K051899

Reference Predicate Device 4 Name: BD 32G x 4mm Pen Needle, K100005

4. Description Of The Device

Unifine® Pentips® and Unifine® Pentips® Plus are sterile, non-toxic, non-pyrogenic, single use pen needles for the subcutaneous injection of drugs from pen injectors. The pen needles are used by consumers, caregivers, and healthcare professionals. They are available in a variety of lengths (4mm, 5mm, 6mm, 8mm and12mm) and gauges (29G, 31G and 32G).

The pen needle assembly consists of a double-ended cannula, a needle hub, a needle shield, primary container and sterility seal that covers the assembly inside the primary container.

The hub has internal threads, which allows the pen needle to be screwed onto a pen injector device. The Non Patient (NP) end of the cannula (inside the hub) penetrates the rubber septum of the cartridge in the pen injector device. The Patient end and NP end of the cannula are lubricated using a silicone based lubricant to aid in injection and penetration into the rubber septum. The inner needle shield is injection molded and assembled over the Patient end of the needle to protect the needle from damage and accidental needle-sticks. The pen needle assembly is then inserted into an injection molded outer container and sealed with a protective peel-away label to ensure a sterility barrier and tamper evidence. The outer container can be used to remove the hub with cannula from the pen injector device after the injection is completed. The peel-away label is pre-printed with information, which includes the lot number, expiry date, and size (length) and gauge of the needle. The individual needle assemblies are then packaged in bags and/or cartons, and placed into shippers with appropriate labeling. The shipper cases are then placed on pallets for sterilization.

Unifine Pentips Plus pen needles differ from Unifine Pentips pen needles because the primary container consists of two 'chambers'. One chamber contains a new, unused pen needle and the second chamber is empty. The empty chamber serves as a built-in pen needle remover, and may prevent accidental needlesticks. Users can insert their used needle into the chamber, then unscrew from the injection pen. The primary container is designed to hold the used pen needle until it can be disposed of in a suitable sharps container. The actual pen needle is identical between Unifine Pentips and Unifine Pentips Plus in both the physical appearance and functionality.

The purpose of this 510(k) Premarket Notification is to obtain Over-the-Counter (OTC) clearance for Unifine Pentips and Unifine Pentips Plus, to add additional needle lengths of 4mm, 5mm & 6mm, and to document some material changes. Though the Indications for Use are worded slightly different, the intended use for Unifine Pentips and Unifine Pentips Plus is substantially equivalent to the primary predicate and multiple predicate devices.

5. Indications for Use

The Unifine Pentips range of pen needles are intended for use with pen injector devices for the subcutaneous injection of drugs, including insulin.

6. Technological Characteristics

A comparison of the intended use and technological characteristics is summarized in the table below, Table 6.1. For the table, the BD Predicates, K051899 & K100005, were combined in the third column as the only difference between the two is the length and gauge of the needle. K051899 included needle lengths of 5mm, 8mm & 12.7mm; and gauge sizes of 31G, 30G & 29G. K100005 covers length of 4mm, and gauge size of 32G.

The changes for Owen Mumford included in this submission are the addition of the lengths (4mm, 5mm & 6mm) and gauge sizes (31G & 32G) to the contract manufactured Unifine Pentip product line. This submission also includes the full range of sizes and gauges self-manufactured by Owen Mumford, including lengths (4mm, 5mm, 6mm, 8mm &12mm) and gauge sizes (32G, 31G & 29G).

The full range of Unifine Pentips and Unifine Pentips Plus pen needles are substantially equivalent to intended use, device description, appearance, function, principle of operation, and basic composition to the predicate devices. Though the sizes and gauges are not exactly the same as the predicate device sizes and gauges, the range of Unifine Pentips and Unifine Pentips Plus (4mm – 12mm, 32G – 29G) fall within the range of the predicate device sizes and gauges (4mm – 12.7mm, 32G – 29G). The sizes included in this submission do not represent a difference in product technology or product performance versus the predicate devices.

Table 6.1: Comparison of Device Characteristics between Submission Devices and Predicate Devices

Device Characteristic	Submission Device: Unifine Pentips & Unifine Pentips Plus (K152339)	Primary Predicate: Unifine Pentips & Unifine Pentips Plus (K973899)	Reference Predicate: Artsana InsuPen® Insulin Pen Needles (K051783)	Reference Predicate: BD Pen Needles (K051899 & K100005)
Intended Use	The Unifine Pentips range of pen needles are intended for use with pen injector devices for the subcutaneous injection of drugs, including insulin.	The Unifine Pentip is single use, disposable hypodermic single lumen needle designed for use with multi-dose injection devices that use prefilled cartridges. The protective paper is removed from the pentip which is then screwed onto the device cartridge housing and then used in the prescribed manner. One of the main uses of the pentip is for use with pen injectors for the delivery of insulin which is supplied in the form of prefilled cartridges. The patient places a fresh pentip needle onto the pen injector, dials a dose, inserts the pentip into the skin and delivers the dose.	Artsana disposable sterile pen needles are used with insulin pen injector devices for the subcutaneous injection of insulin in the treatment of diabetes.	BD Pen Needle is intended for use with pen injector device for subcutaneous injection of drugs, including insulin and exenatide.
Prescription or OTC	OTC	Prescription	Prescription	OTC
Operation Principle	Manual	Manual	Manual	Manual
Design/ Construction	Needle assembly (cannula, needle hub, needle shield, outer container)	Needle assembly (cannula, needle hub, needle shield, outer container)	Needle assembly (cannula, needle hub, needle shield, outer container)	Needle assembly (cannula, needle hub, needle shield, outer container)
Materials	*Unifine Pentips by Artsana S.p.A.:* • Cannula – Stainless Steel • Lubricant – Silicone • Adhesive – Medical Grade	*Unifine Pentips by Artsana S.p.A.:* • Cannula – Stainless Steel • Lubricant – Silicone • Adhesive – Medical Grade	• Cannula – Stainless Steel • Lubricant – Silicone • Adhesive – Medical Grade Adhesive • Needle Hub –	• Cannula – Stainless Steel • Lubricant – Silicone Based • Outer Container – Polypropylene *Note: this is the information publicly*

Device Characteristic	Submission Device: Unifine Pentips & Unifine Pentips Plus (K152339)	Primary Predicate: Unifine Pentips & Unifine Pentips Plus (K973899)	Reference Predicate: Artsana InsuPen® Insulin Pen Needles (K051783)	Reference Predicate: BD Pen Needles (K051899 & K100005)
	Adhesive • Needle Hub - Polypropylene • Needle Shield – High Density Polyethylene • Outer Container – High Density Polyethylene • Sterility Seal – Paper Laminate *Unifine Pentips by Owen Mumford:* • Cannula – Stainless Steel • Lubricant – Silicone • Adhesive – Medical Grade Adhesive • Needle Hub – Polypropylene • Needle Shield – High Density Polyethylene • Outer Container – High Density Polyethylene • Sterility Seal – Paper Laminate *Unifine Pentips Plus by Owen Mumford:* • Cannula – Stainless Steel • Lubricant – Silicone • Adhesive – Medical Grade Adhesive • Needle Hub – Polypropylene • Needle Shield – High Density Polyethylene • Outer Container – Polypropylene • Sterility Seal – Paper Laminate	Adhesive • Needle Hub - Polypropylene • Needle Shield – High Density Polyethylene • Outer Container – High Density Polyethylene • Sterility Seal – Paper Laminate	Polypropylene • Needle Shield – High Density Polyethylene • Outer Container – High Density Polyethylene • Sterility Seal – Paper Laminate	*available for these devices.*
Package	• Plastic outer container • Sterility Seal • Shelf box	• Plastic outer container • Sterility Seal • Shelf box	• Plastic outer container • Sterility Seal • Shelf box	• Plastic outer container • Sterility Seal • Shelf box

Device Characteristic		Submission Device: Unifine Pentips & Unifine Pentips Plus (K152339)	Primary Predicate: Unifine Pentips & Unifine Pentips Plus (K973899)	Reference Predicate: Artsana InsuPen® Insulin Pen Needles (K051783)	Reference Predicate: BD Pen Needles (K051899 & K100005)
Needle Specifications	*Needle Length*	*Unifine Pentips manufactured for Owen Mumford Ltd:* 4mm for 32G; 5mm, 6mm, 8mm for 31G; 12mm for 29G *Unifine Pentips by Owen Mumford*: 4mm for 32G; 5mm, 6mm and 8mm for 31G; 12mm for 29G *Unifine Pentips Plus by Owen Mumford*: 4mm for 32G; 5mm, 6mm and 8mm for 31G; 12mm for 29G	*Unifine Pentips manufactured for Owen Mumford Ltd:*: 8mm for 31G; 12mm for 29G	4mm for 33G, 4mm, 6mm and 8mm for 32G, 8mm for 30G, 5mm, 6mm and 8mm for 31G, 12mm for 29G	4mm for 32G, 5mm and 8mm for 31G and 12.7mm for 29G
	Effective Gauge	29G, 31G and 32G	29G and 31G	29G, 30G, 31G, 32G and 33G	29G, 31G and 32G
	Tip Configura-tion	Patient-side: Tri-bevel (3)	Patient-side: Tri-bevel (3)	Patient-side: Tri-bevel (3)	Patient-side: 5 bevel
Sterilization		*Unifine Pentips manufactured for Owen Mumford Ltd:* Ethylene Oxide (validated to achieve SAL 10^{-6}) *Unifine Pentips by Owen Mumford:* Gamma Radiation (validated to achieve SAL 10^{-6}) *Unifine Pentips Plus by Owen Mumford:* Gamma Radiation(validated to achieve SAL 10^{-6})	*Unifine Pentips manufactured for Owen Mumford Ltd:* Ethylene Oxide (validated to achieve SAL 10^{-6})	Ethylene Oxide (validated to achieve SAL 10^{-6})	Gamma Radiation

Though there are minor differences in the Indications for Use between the Predicate Device, Reference Predicate Devices and the Submission Device, the intended use is substantially equivalent. The differences are that the Predicate Device uses terminology of "for use with multi-dose injection devices that use pre-filled cartridges" and the Submission Device uses terminology of "pen injector devices for the subcutaneous injection of drugs, including insulin". Multi-dose injection pens used with pre-filled cartridges were the injectors available at the time of the original 510(k). Since that time injector pens that are disposable that include the pre-filled cartridge have become prevalent in the market. Both injectors operate using the same principle, a pen needle is screwed onto the end and the drug is then injected.

We have tested our pen needles with both a re-useable pen injectors (which we referred to as "multi-dose injection device" in the original 510(k)) and disposable pen injectors. Our pen needles operate as intended on both re-useable pen injectors and disposable pen injectors.

The differences in the Indications for Use do not affect performance of the devices, or the safety and effectiveness of the devices. Therefore, Unifine Pentips and Unifine Pentips Plus are substantially equivalent to the Predicate Device and the Reference Predicate Devices in the device characteristics.

7. Performance Data

Non-clinical Performance Data:

The following performance data were provided in support of the substantial equivalence determination.

Bench testing

Table 7.1: List of Performance Tests to Standards

Test	Standard	Result
Dimensions for needles	ISO 11608-2:2012 Section 4.2.2	Meets standard
Needle points	ISO 11608-2:2012 Section 4.5	Meets standard
Freedom from defects	ISO 11608-2:2012 Section 4.6	Meets standard
Lubrication	ISO 11608-2:2012 Section 4.7	Meets standard
Dislocation of measuring point at patient end	ISO 11608-2:2012 Section 4.8	Meets standard
Bond between hub and needle tube	ISO 11608-2:2012 Section 4.4	Meets standard
Ease of assembly/ disassembly	ISO 11608-2:2012 Section 4.10	Meets standard
Sterilization	ISO 11608-2:2012 Section 4.11, ISO 11137-2:2007 (manufactured pen needles in the UK), ISO 11135-1:2006(manufactured pen needles in Italy)	Meets standard
Flow rate	ISO 11608-2:2012 Section 4.3	Meets standard
Needle dose accuracy	ISO 11608-2:2012 Section 4.9, 11.4.2	Meets standard
Needle hub torque removal	ISO 11608-2:2012 Section 4.9, 11.4.3	Meets standard

Additionally, performance testing other than the above ISO Standards was performed on the devices. The devices comply with the acceptance criteria established based on the specifications of the devices.

Table 7.2: List of Internal Performance Tests

Performance Test	Results
Force required to remove pen needle from primary container	Meets acceptance criteria
Force required to fit pen needle into primary container (UP)	Meets acceptance criteria
Force to remove needle shield from pen needle	Meets acceptance criteria

The results of these tests demonstrate that the Unifine Pentips and Unifine Pentips Plus devices perform equivalent to the predicate devices when used as intended.

Biocompatibility

In accordance with ISO 10993-1, Unifine Pentips and Unifine Pentips Plus are classified as: Externally Communicating Device, Blood Path Indirect, Short Term (<24 hours) Use, as the cannula is immediately withdrawn after injection into the body. The biocompatibility evaluation for finished devices' blood/body contacting parts were conducted in accordance with the FDA Blue Book Memorandum #G95-1 "*Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*,'" May 1, 1995, and International Standard ISO 10993-1 "*Biological Evaluation of Medical Devices – Part 1:*

Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity
- Hemocompatibility
- LAL & Rabbit Material Mediated Pyrogen Testing

Results of the testing demonstrate the devices are biocompatible.

Sterilization

The sterility of the devices is assured using a sterilization method validated in accordance with ISO 11137 – Medical Devices – Validation and Routine Control of Radiation Sterilization for Unifine Pentips and Unifine Pentips Plus manufactured by Owen Mumford UK. The sterility of Unifine Pentips manufactured for Owen Mumford by Artsana S.p.A. is assured using a sterilization method validated in accordance with ISO 11135 – Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization. Through both sterilization methods used, all Unifine Pentips and Unifine Pentips Plus are sterilized to provide a Sterility Assurance Level (SAL) of 10^{-6}.

8. Clinical Data

Clinical Data per 807.92(b)(2) was not required to establish substantial equivalence for these devices.

9. Conclusions

In summary, the Unifine Pentips and Unifine Pentips Plus devices, subject of this 510(k), are substantially equivalent in their intended use, technology/principle of operation, materials, and performance to the predicate devices.