July 11, 2018

Owen Mumford Ltd
% Patty Cronan
Quality Manager
Owen Mumford USA Inc
1755 West Oak Commons CT
Marietta, Georgia 30062

Re: K173881
Trade/Device Name: Unifine SafeControl
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: May 24, 2018
Received: May 25, 2018

Dear Patty 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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Alan M. Stevens -S

Digitally signed by Alan M. Stevens -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300189211, cn=Alan M. Stevens -S
Date: 2018.07.11 07:16:33 -04'00'

for Tina Kiang, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173881

Device Name
Unifine SafeControl™

Indications for Use *(Describe)*
The Unifine SafeControl™ range of pen needles are intended for use with multi-dose injection devices for the subcutaneous injection of FDA approved 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

1.Submitter

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Date Prepared: 15 DECEMBER 2017

2.Device

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

3.Predicate Devices

Predicate Device Name: Unifine Pentips and Unifine Pentips Plus, 510k number K152339

4.Description of The Device

The Unifine SafeControl™ safety pen needle is a sterile, single-use, disposable device intended for use with multi-dose Injector devices for the subcutaneous injection of FDA approved drugs, including insulin. The device is designed for prescription and over-the-counter use and to be used by self-administering patients, care-givers and healthcare professionals. The safety pen needle is a 30-gauge needle available in sizes between 5mm and 8mm lengths.

The target population includes male and female right or left-handed self-administering patients, care givers and healthcare professionals. The frequency of use and intended patient population is dependent on given treatment regime.

The pen needle assembly consists of a cannula attached to a needle carrier assembled into a plastic moulded needle hub and safety guard, a primary container that houses the entire assembly and a sterility seal that covers the assembly inside the primary container. The entire device is packaged and labeled as a sterile single-use device.

The purpose of this 510(k) Premarket Notification is to obtain a Prescription Use and Over-The-Counter Use clearance for the Unifine SafeControl™ safety pen needle device. The intended use for the Unifine SafeControl™ remains the same as the predicate device.

Figure 5.1: Exploded view of the Unifine SafeControl™ safety pen needle assembly

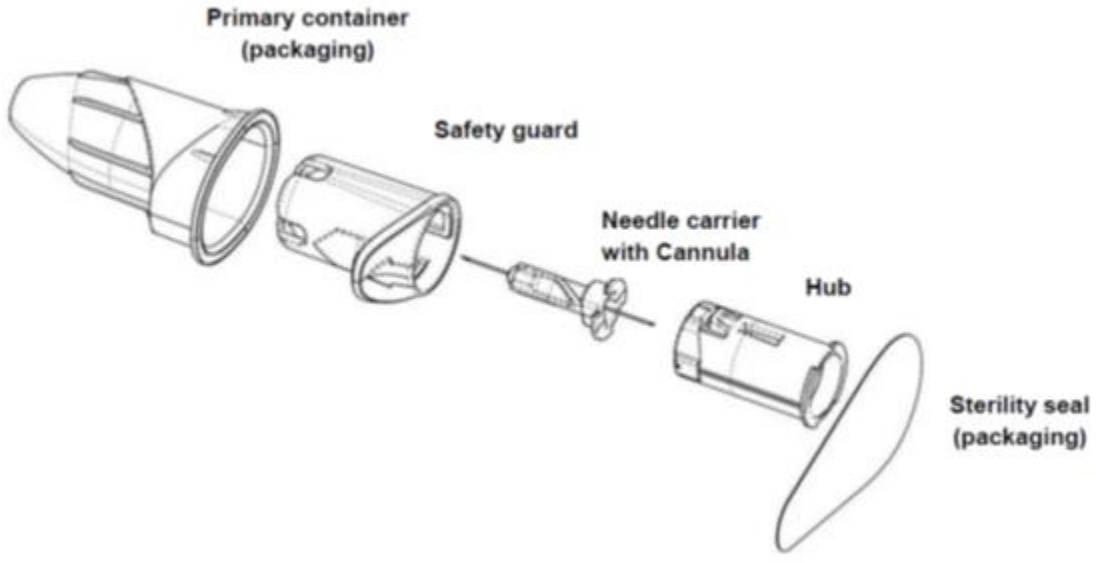

Table 5.1: Biocompatibility Device Categorization for Submission Device Components

Component	Base Material	Patient Contact	Duration
Hub	Polypropylene	Surface (Intact Skin)	A - Limited (≤24 hour)
Safety Guard	Polystyrol	Surface (Intact Skin)	A - Limited (≤24 hour)
Needle Carrier	Polypropylene	Surface (Intact Skin)	A - Limited (≤24 hour)
Cannula 30G	STAINLESS STEEL – AISI 304 coated with silicone	Externally Communicating (Bloodpath Indirect)	A - Limited (≤24 hour)
Adhesive (Glue)	DYMAX 1180-M-SV04	Surface (Intact Skin)	A - Limited (≤24 hour)
Primary Packaging			
Primary Container (Packaging)	Polypropylene	Surface (Intact Skin)	A - Limited (≤24 hour)
Foil seal (Packaging)	Paper Laminate	Surface (Intact Skin)	A - Limited (≤24 hour)

5.Indications for Use

The Unifine SafeControl™ range of pen needles are intended for use with multi-dose injection devices for the subcutaneous injection of FDA approved drugs, including insulin.

6. Technological Characteristics

The Unifine SafeControl™ safety pen needles are substantially equivalent to the predicate device with an additional safety feature allowing the exposed needle to be covered after use.

A comparison of the intended use and technological characteristics is summarized in the table below.

Table 5.2: Comparison of Device Characteristics between Submission Devices and Predicate Device

Device Characteristic	**Predicate Device: Unifine Pentips & Unifine Pentips Plus – K152339**	**Submission Device - Unifine SafeControl™**
Intended Use	The Unifine Pentips range of pen needles are intended for use with multi-dose injection devices for the subcutaneous injection of FDA approved drugs, including insulin	Unchanged from the predicate device
Operating principle	Manual	Manual with an additional safety feature allowing the exposed needle to be covered after use.
Design/ construction	Needle assembly (cannula, needle hub packaged in a needle shield and primary container)	Device unchanged from the predicate device with the exception of an addition of a safety feature (safety guard) integrated in the device. The needle carrier was integrated in the needle hub in the predicate device.
Components and Materials	*Unifine Pentips by Owen Mumford:* *Device:* • Cannula – Stainless Steel • Lubricant – Silicone • Adhesive – Medical Grade Adhesive • Needle Hub – Polypropylene *Packaging:* • Needle Shield – High Density Polyethylene • Outer Container – High Density Polyethylene • Sterility Seal – Paper Laminate *Unifine Pentips Plus by Owen Mumford:* *Device:* • Cannula – Stainless Steel • Lubricant – Silicone • Adhesive – Medical Grade Adhesive • Needle Hub – Polypropylene *Packaging:* • Needle Shield – High Density Polyethylene • Primary Container – Polypropylene • Sterility Seal – Paper Laminate	Unchanged from the predicate device with the exception of a safety feature (safety guard) component: • Safety guard – Polystyrol The needle carrier was integrated in the needle hub in the predicate device, the colour additive is changed.
Package	• Plastic outer container • Sterility Seal • Shelf box	Unchanged from the predicate device

Needle Specification	Needle Length	*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	5mm for 30G 8mm for 30G
	Effective Gauge	29G, 31G and 32G	30G
	Tip Configuration	Patient-side: Tri-bevel (3)	Unchanged from the predicate device
Sterilization		*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})	Unchanged from the predicate device, Gamma Radiation (validated to achieve SAL 10^{-6}).

7.Performance Data

Non-clinical performance data:

To support this submission, design verification testing was performed to demonstrate that the device operates safely and effectively. The following table shows a summary of the performance tests to standards.

Bench Testing:

Table 5.3: Summary of the performance tests to standards:

Test	**Standard/ Requirement**	**Results**
Visual Inspection	ISO 11608-2:2012 Section 12.2.2	Meets standard
Torque to attach to pen	ISO 11608-2:2012 Section 11.4.1.5	Meets standard
Torque to remove from pen	ISO 11608-2:2012 Section 11.4.3	Meets standard
Dose accuracy	ISO 11608-2:2012 Section 11.4.2	Meets standard
Flow Rate	ISO 11608-2:2012 Section 4.3	Meets standard
Force to over-ride safety feature	ISO 11608-5:2012 Section 5.1.11.2	Meets standard
Needle Retention	ISO 11608-2:2012 Section 9	Meets standard
Needle Dislocation	ISO 11608-2:2012 Section 4.8	Meets standard
Sterility – Seal integrity	ISO 11607-1:2007 Section 6.3	Meets standard
Internal pressure test (Burst Testing)	ASTM-F-1140-07:2007 ASTM 4169 2016 Section 16.2	Meets standard
NIS Compatibility	ISO 11608-2:2012 Section 4.9	Meets standard
Simulated Clinical use testing (sharps safety testing)	ISO 23908:2011 & Guidance for Industry and FDA Staff-Medical Devices with Sharps Injury Prevention Features	Meets standard

The objective of all the bench testing conducted was to verify that the submission device met the pre-determined specifications, in order to support the conclusion that it is fit for purpose and is substantially equivalent. Where applicable, the testing for the submission device was conducted in accordance with IS0 11608-2:2012 Needle-based injection systems for medical use – Requirements and test methods – Part 2: Needles. Written protocols specified the scope, objectives, specifications, test equipment, test methods and acceptance criteria. Additional design verification testing was performed that was not required by ISO 11608- 2:2012. The type of Bench testing are summarized below.

The following are the tests conducted:

• Visual Inspection
• Torque to attach to pen
• Torque to remove from pen
• Dose accuracy
• Glide Force
• Penetration Force
• Force to remove foil
• Flow Rate
• Force to activate safety feature
• Force to over-ride safety feature
• Needle Retention
• Needle Dislocation
• Sterility – Seal integrity
• Internal pressure test
• Force to remove from Primary Container
• Torque to Break Thread Bond

Biocompatibility:

In accordance with ISO 10993-1, the Unifine SafeControl™ safety pen needle is classified as: Externally Communicating Device, Blood Path Indirect, Limited (≤24 hour) use. The biocompatibility evaluation for finished devices' blood/body contacting parts were conducted in accordance with the FDA guidance document "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", 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 tests used for the biocompatibility evaluation of the contact materials are as follows:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity
- Hemocompatibility
- Pyrogenicity

In addition to the tests set out in ISO 10993-1: the submission included evaluation of Pyrogenicity (ISO 10993-11 Annex F) and the whole device evaluation (ISO 10993-1 section 7). Pyrogenicity testing shall be considered for any components which come into internal contact with the user, classed as externally communicating. Full device evaluation includes a review of all the materials, consumables, manufacturing processes and environments by an expert toxicologist to ensure the device in its final form is biocompatible.

Results of the testing demonstrate the materials are biocompatible.

Sterilization:

Unifine SafeControl™ safety pen needles manufactured by Owen Mumford in the UK are sterilized by gamma radiation. A summary of sterilization and shelf life details for all variants of device are as follows:

Sterilization Method: Gamma radiation

Radiation dose range: 20-40kGy

Description of the method used to validate the sterilization cycle:

Sterilization validation (Dose mapping) was conducted in accordance with Section 9 of *ISO 11137: "Sterilization of Healthcare Products – Radiation – Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices."*

Shelf life

Shelf life studies were conducted per ISO 11608-2, ISO 23908, and ASTM F1980-16 to support an initial 2-year shelf life, and protocols were submitted to support an increase to a 5-year shelf life upon successful completion of studies.

8.Conclusion

In summary, the differences between the Unifine SafeControl™ and the predicates do not raise different questions of safety and effectiveness and the performance data shows that the device is substantially equivalent to the predicate device.