September 17, 2021

Owen Mumford Ltd
Darren Mansell
Regulatory Affairs Manager
Brook Hill
Woodstock, Oxfordshire OX20 1TU
United Kingdom

Re: K210399
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: August 20, 2021
Received: August 23, 2021

Dear Darren Mansell:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

For CAPT Alan Stevens
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210399

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.

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

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SECTION 6.0
SPECIAL 510(k) SUMMARY: 510k Number: K210399

1. Submitter

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Date Prepared: 17 September 2021

2. Device

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

3. Predicate Devices

The predicate device, Unifine SafeControl™ by Owen Mumford Ltd, was approved under K173881.

The new needle lengths and gauge sizes presented in this submission have not been previously submitted.

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, caregivers and healthcare professionals. The safety pen needle is currently available in 30-gauge size with 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 labelled as a sterile single-use device.

The purpose of this Special 510(k) Premarket Notification is to increase the range of Unifine SafeControl™ safety pen needle devices to include gauge sizes of 31G and 32G in 4, 5, 6, and 8mm lengths.

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 the exception of the gauge sizes and needle lengths as

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

Table 8: Comparison of Device Characteristics between Submission Devices and Predicate Device

Device Characteristic	Predicate Device	Submission Device	Comment
Intended 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	Unchanged from the predicate device	The characteristic is identical
Operating principle	Manual with an additional safety feature allowing the exposed needle to be covered after use.	Unchanged from the predicate device	The characteristic is identical
Design/ Construction	Needle assembly (cannula, needle hub packaged in a needle shield and primary container). The safety guard is integrated into the device.	Unchanged from the predicate device	The characteristic is identical
Components and Materials	• Cannula – Stainless Steel • Lubricant – Silicone • Adhesive – Medical Grade Adhesive • Needle Hub – Polypropylene • Needle Shield – High Density Polyethylene • Safety guard- Polystryol • Outer Container – High Density Polyethylene • Sterility Seal – Paper Laminate	Unchanged from the predicate device	The characteristic is identical
Package	• Plastic outer container: • Sterility Seal • Shelf box	Unchanged from the predicate device	The characteristic is identical
Shelf life	5 years	5 years	The characteristic is identical
Needle Sizes and Gauges	5mm x 30G 8mm x 30G	8mm x 31G 6mm x 31G 5mm x 31G 4mm x 32G	The characteristic is different – the submission device presents different needle lengths and gauges. The different needle lengths and gauges were addressed through the bench testing summarised in Table 9 of this document.

7. Performance Data

Non-clinical performance data:
Risk management was performed to identify required verification/validation testing needed to support the introduction of the new needle lengths and gauges. 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 9: Summary of the performance tests to standards:

Test	Standard/ Requirement	Results
Visual Inspection	ISO 11608-2:2012 Section 12.2.2 and as per protocols used in K173881	Meets standard
Needle Retention	ISO 11608-2:2012 Section 9 and as per protocols used in K173881	Meets standard
Glide Force	As per protocols used in K173881	Meets standard
Penetration Force	As per protocols used in K173881	Meets standard
Flow Rate	ISO 11608-2:2012 Section 4.3 and as per protocols used in K173881	Meets standard
Needle Dislocation	ISO 11608-2:2012 Section 4.8 and as per protocols used in K173881	Meets standard
Accelerated Aging	ISO 11608-2:2012 and as per protocols used in K173881	Meets standard
Real Time Aging	ISO 11608-2:2012 and as per protocols used in K173881	Ongoing

Biocompatibility:
The biocompatibility of the device is governed by the materials used, which have not been changed as a result of the additional needle gauge sizes and lengths. Therefore, the biocompatibility reports presented in K173881 are still valid and no additional testing is required.

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 SafeControl™ manufactured by Owen Mumford UK. Through the sterilization methods used, all Unifine SafeControl™ devices are sterilized to provide a Sterility Assurance Level (SAL) of 10^{-6}.

8. Conclusion

In summary, Table 8 in this document indicates that the characteristics between the submission device and the predicate device are identical, with the exception of the additional needle lengths and gauges presented in the submission device.

The results of the bench testing, summarised in Table 9 of this document, demonstrate that the differences between the submission Unifine SafeControl™ and the predicate (additional needle lengths and gauges) have no impact on safety and effectiveness and the product is therefore substantially equivalent to the predicate device.