December 16, 2021

UltiMed Incorporated
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K213407
Trade/Device Name: UltiCare Disposable Pen Needles
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic single lumen needle
Regulatory Class: Class II
Product Code: FMI
Dated: October 18, 2021
Received: October 19, 2021

Dear Prithul Bom:

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,

CAPT Alan M. 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)*

K213407

Device Name
UltiCare™ Disposable Pen Needles

Indications for Use *(Describe)*
The UltiCare™ Disposable Pen Needles are used with pen injector devices for the subcutaneous injection of drugs.

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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5.0 TRADITIONAL 510(K) SUMMARY

Submitted by:	UltiMed Inc. 350 Highway 7, Suite 100 Excelsior, MN 55331
Contact Person:	Cori Ragan Principal Advisor Labcorp 5353 Wayzata Boulevard, Suite 505 Minneapolis, Minnesota 55416 Telephone: 612-268-8746 Cori.Ragan@labcorp.com
Date of Summary:	15 December 2021
Device Trade Name:	UltiCare™ Disposable Pen Needles
Common or Usual Name:	Pen Needles
Regulation Number:	21 CFR §880.5570
Classification Name:	Hypodermic single lumen needles
Product Code:	FMI
Device Classification:	II
Review Panel:	General Hospital
Predicate/ Reference Device(s):	Predicate Device - K162516 – BD pen needles Reference Device – K100812 - UltiCare™ Disposable Pen Needles
Model Numbers:	71006 (29G, 12.7mm) 61005 (30G, 5mm) 61008 (30G, 8mm) 71013 (31G, 5mm) 71004 (31G, 6mm) 71005 (31G, 8mm) 71003 (32G, 4mm) 71014 (32G, 6mm)

Device Description: The UltiCare™ Disposable Pen Needles are sterile, single-use, hypodermic single lumen needles designed for use with pen injectors for subcutaneous injection of a desired dose of drugs approved for delivery using a pen needle. The UltiCare™ Disposable Pen Needles consist of a double-ended cannula, a needle hub, a needle shield and the needle primary container. The UltiCare™ Disposable Pen Needles are non-toxic and are available in a variety of needle sizes (29 gauge to 32 gauge) and lengths (5/32" to 1/2").

Intended Use: The UltiCare™ Disposable Pen Needles are used with pen injector devices for the subcutaneous injection of drugs.

Technological Characteristics: A comparison of characteristics of UltiCare Disposable Pen Needles and the predicate device is shown in the table below.

Table 5-1: Characteristic Comparison

Feature	UltiCare™ Disposable Pen Needle (Pending)	BD Pen Needle (K162516)	Conclusion
Product Code	FMI	FMI	Identical
Device Description	Pen needle	Pen needle	Identical
Design Needle and Hub			Similar
Intended use(s)	The UltiCare™ Disposable Pen Needles are used with pen injector devices for the subcutaneous injection of drugs.	BD Pen Needle is intended for use with pen injector devices for the subcutaneous injection of drugs.	Identical
Type of use	Over-the Counter Use	Over-the Counter Use	Identical
Specific drug use	Drugs	Drugs	Identical
Tip type	Center tip	Center tip	Identical
Needle lumen	Single Lumen	Single Lumen	Identical
Needle gauge (mm)	32 G (0.23 mm) to 29 G (0.33 mm)	32 G (0.23 mm) to 29 G (0.33 mm)	Identical
Needle length in inches (mm)	5/32" (4 mm) to 1/2" (12.7 mm)	5/32" (4 mm) to 1/2" (12.7 mm)	Identical
Needle connector type	Compatible with pen injectors that comply with ISO 11608-1	Compatible with pen injectors that comply with ISO 11608-1	Identical
Biocompatibility	Conforms to ISO 10993-1	Conforms to ISO 10993-1	Identical
Sterilization	Ethylene Oxide (EtO)	Gamma Irradiation	Different

Feature	UltiCare™ Disposable Pen Needle (Pending)	BD Pen Needle (K162516)	Conclusion
Method of attachment to pen injector	Screw threads	Screw threads	Identical
Sterility	SAL = 10^{-6}	SAL = 10^{-6}	Identical
Needle	Stainless Steel 304	Stainless Steel	Identical
Needle cover (primary container)	High-Density polyethylene	Unknown	Unknown

Purpose of the reference device:
The design of the needle and hub as well as the needle cover (primary container) materials and dimensions of the subject device were leveraged from the reference device. All test methods used on the reference device for biocompatibility, performance, shelf life, sterilization, distribution, and package integrity were leveraged for the subject device.

Non-Clinical Performance Data:
UltiCare Disposable Pen Needles successfully passed all the required non-clinical testing which included the following:

- Testing to evaluate particulates per USP <788>
- Testing for compliance with the requirements of 11608-2:2012 Needle-based injection systems for medical use -- Requirements and test methods -- Part 2: Needles
- The table below presents the requirements of the 11608-2:2012 Needle-based injection systems for medical use -- Requirements and test methods -- Part 2: Needles standard and the result of the testing conducted.

Table 5-2: Requirements of 11608-2:2012

Test Parameter	Clause no. & requirement of ISO 11608-2:2012	Results
Materials	**4.1** The needle shall be made of tubing materials specified in ISO 9626.	Meets requirements
Dimensions	**4.2** The needles shall fit the test apparatus specified in item 7.3 of ISO 11608-2.	Meets requirements
Determination of flow rate through the needle	**4.3** The needle was tested in accordance with Annex A to ISO 11608-2 to determine flow rate through the needle.	Meets requirements
Bond between hub and needle tube	**4.4** The union of the hub and needle tube shall not break when tested in accordance with Clause 9 of ISO 11608-2.	Meets requirements
Needle points	**4.5** When examined under a magnification of x2,5, needle points shall appear sharp and free from feather edges, burrs and hooks.	Meets requirements
Freedom from defects	**4.6** The needle tube shall fulfill the requirements of ISO 7864, 11.3.	Meets requirements
Lubrication	**4.7** The needle tube should be lubricated at both the patient end and the cartridge end. The lubricant shall not, under normal or corrected-to-normal vision, be visible as droplets of fluid on the outside surface of the needle tube.	Meets requirements
Dislocation of measuring point at patient end	**4.8** Dislocation of the cannula point at the patient end shall be in accordance with ISO 11608-2 Table 2 when tested as per Clause 8 (of ISO 11608-2).	Meets requirements
Determination of functional compatibility with needle-based injection systems	**4.9** Compatibility with any NIS shall be claimed only after testing in accordance with Clause 11.	Meets requirements
Ease of assembly and disassembly	**4.10** Attachment of the needle shall be possible without removing the needle from its opened unit packaging. Compliance is checked according to the requirements of Clause 11.	Meets requirements
Sterility	**4.11** The needle in its unit packaging shall has been subjected to a validated sterilization process.	Meets requirements
Pre-conditioning of needles	**6** All requirements of the standard related to preconditioning of needles were met.	Meets requirements

Biocompatibility testing:	The Biological Tests selected to be performed on the sterile final product that has direct contact with the end-user according to the 2020 FDA guidance Use of International Standard ISO 10993- 1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" considering contact type and duration were as follows: 1. Cytotoxicity 2. Sensitization 3. Irritation or Intracutaneous Reactivity 4. Acute Systemic Toxicity 5. Material-Mediated Pyrogenicity 6. Hemocompatibility 7. Subacute/subchronic toxicity Biocompatibility tests selected as per the requirements of FDA guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" considering contact type and duration for the UltiCare Disposable Pen Needles did not show any adverse biological / biocompatibility reactions.
Clinical Performance Data:	Clinical data is not required.
Conclusion:	Testing has demonstrated that UltiCare Disposable Pen Needles are substantially equivalent to the predicate device.