DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 9, 2015

UltiMed Incorporated
c/o Mary Beth Henderson, Ph.D.
Regulatory & Clinical Research Institute, Incorporated.
VP Regulatory Affairs and Quality Systems
5353 Wayzata Boulevard, Suite 505
Minneapolis, MN 55416

Re: K140949
Trade/Device Name: UltiMed UltiCare™ 3mL Luer Lock Safety Syringes with Needle
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG, FMF, FMI
Dated: January 30, 2015
Received: February 2, 2015

Dear Dr. Henderson:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K140949

Device Name
UltiCare™ 3mL Luer Lock Safety Syringe with Needle

Indications for Use *(Describe)*

The UltiCare Safety Syringe is intended to inject fluid into, or withdraw fluid from the body. The safety mechanism aids in the prevention of needle stick injuries.

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.

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5.0 TRADITIONAL 510(K) SUMMARY

K140949

Submitted by:

UltiMed Inc.
350 Hwy 7, Suite 100
Excelsior, MN 55331

Contact Person:

Thomas Sauro

Telephone: 651-291-7909 x 206

Date of Summary: December 05, 2014

Device Trade Name: UltiMed UltiCare™ 3 mL Luer Lock Safety Syringes with Needle

Common or Usual Name: Syringe with Sharps Injury Prevention Feature

Classification:

Piston Syringe	§ 880.5860	FMF	Class II
Anti-stick Syringe	§ 880.5860	MEG	Class II
Hypodermic Single Lumen Needle	§ 880.5570	FMI	Class II

Predicate Device:
UltiCare Safety Syringe (K080600)
Sherwood (Tyco) Monoject® Safety Syringe (K922522)

Device Description:

The UltiCare™ 3 mL Luer Lock Safety Syringes with Needle is a standard piston type syringe with a removable needle and protective shield.

This sterile, single-use, disposable 3 ml piston syringes consist of a syringe barrel, plunger rod with gasket, removable single lumen needle, needle cap, and protective shield. The UltiCare Safety Syringes are non-toxic and non-pyrogenic, and will be available in a range of needle gauges and lengths between the smallest (27G x 5/16”) and the largest (21G x 1 1/2”).

Intended Use:

The UltiCare™ Safety Syringe is intended to inject fluid into, or withdraw fluid from the body. The safety mechanism aids in the prevention of needle stick injuries.

Technological Characteristics:

The UltiCare™ 3 mL Luer Lock Safety Syringes with Needle is an extension of the UltiCare Safety Syringe product line and is substantially equivalent in device description, function, principle of operation, and basic composition to the predicate device. The subject and predicate devices consist of a syringe barrel, plunger rod with gasket, removable single lumen needle, needle cap, and protective shield.

The UltiCare Safety Syringe product line safety shield is made of clear plastic and is furnished in a retracted position (with the needle cap over the needle). After use of the syringe, the protective shield is engaged by sliding it away from the finger grip to an extended position over the needle and rotated to lock in place.

Testing:

The subject UltiCare 3 mL Luer Lock Safety Syringes with Needle have been designed and tested to meet the requirements of voluntary standards and FDA guidance documents applicable to the subject and predicate devices. Results of the non-clinical testing support the conclusion of substantial equivalence to the UltiCare Safety Syringes to the predicate devices.

Performance Testing:

The subject UltiCare 3 mL Luer Lock Safety Syringes with Needle have been designed and successfully tested to meet the applicable requirements outlined in ISO 594, ISO 6009, ISO 7864, ISO 7886-1, ISO 8537, and ISO 9626.

Biocompatibility Testing:

The subject UltiCare Safety Syringe body is produced using the same manufacturing processes and uses the same materials, dyes/inks, manufacturing process, adhesives, and sterilization process/cycle as the previously cleared UltiCare Safety Syringes (K080600); therefore additional biocompatibility testing to ISO 10993 standards is not required.

The removable needles are considered externally communicating devices with limited duration contact with circulating blood, and have been tested to meet the biocompatibility requirements of ISO 10993 to include cytotoxicity, sensitization, irritation/intracutaneous reactivity, acute systemic toxicity testing, and hemocompatibility.

Sterilization and Shelf-life Testing:

Sterilization of the UltiCare Safety Syringes is validated using the Half Cycle method as outlined in ISO 11135. The maximum levels of residues of ethylene oxide and ethylene chlorohydrin will not exceed the limits presented in ISO 10993-7.

Pyrogenicity Testing:

The UltiCare 3 mL Luer Lock Safety Syringes with Needle have successfully passed pyrogenicity testing (USP <151> Rabbit Method).

Clinical Data:

No prospective clinical trials were conducted in support of this Traditional 510(k).

Substantial Equivalence: The major similarities of the UltiCare Safety Syringe with Removable Needle to the predicate devices support the substantial equivalence in intended use, principles of operation, function and basic composition. The non-clinical testing to voluntary standards and applicable FDA guidances provide additional evidence the subject UltiCare Safety Syringe is substantially equivalent to the predicate devices in terms of safety, efficacy, and performance.

The minor differences between the subject UltiCare Safety Syringe and the predicate devices do not raise new issues of safety or effectiveness.