K103011



FEB - 2 2011

# 5.0 TRADITIONAL 510(K) SUMMARY

**Submitted by:**

UltiMed Inc.
287 East Sixth Street, Ste 380
St. Paul, MN 55101

**Contact Person:**

Mary Henderson, Ph.D.
Principal Advisor
Regulatory & Clinical Research Institute, Inc.
5353 Wayzata Boulevard, Suite 505
Minneapolis, Minnesota 55416
952-227-3380
mbhenderson@rcri-inc.com

**Date of Summary:**

December 9, 2010

**Device Trade Name:**

UltiCare™ Safety Insulin Syringe

[Numerous sizes and combinations varying between the smallest (0.3 ml x 31G x $^{5}/_{16}$") and the largest (1 ml x 29G x $^{1}/_{2}$")]

**Common or Usual Name:**

Syringe with Sharps Injury Prevention Feature

**Classification:**

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

**Predicate Device(s):**

K080600: UltiMed UltiCare™ Safety Syringe
K922522: Sherwood (Tyco) Monoject® Safety Syringe (Model Monoject Insulin Safety Syringe)

**Device Description:**

The UltiCare Safety Insulin Syringe is a standard piston type syringe with permanently attached (uni-body) needle and protective shield.

These syringes are sterile, single-use, disposable piston syringes consisting of a syringe barrel calibrated in units of insulin (U-100), plunger rod with gasket, permanently attached single lumen needle, needle cap, and protective shield. The UltiCare Safety Insulin Syringes are non-toxic and non-pyrogenic, and will be available in numerous sizes and combinations between the smallest (0.3 ml x 31G x $^{5}/_{16}$") and the largest (1 ml x 29G x $^{1}/_{2}$").

**Intended Use:**

The UltiCare Safety Insulin Syringe is intended to inject U-100 insulin into the body. The safety mechanism aids in the prevention of needle stick injuries.

**Technological Characteristics:**

The UltiCare Safety Insulin Syringe is substantially equivalent in device description, function, principle of operation, and basic composition to the predicate devices. The subject device and the predicate devices consist of a syringe barrel, plunger rod with gasket, permanently attached single lumen needle, needle cap, and protective shield.

The protective shield is identical to the currently marketed UltiCare Safety Syringe (K080600). It is made of clear plastic and is furnished in a retracted position with the needle cap over the needle. When the needle cap is removed, insulin can be drawn and injected in the conventional manner. After the injection, the protective shield is engaged by sliding it away from the finger grip to an extended position over the needle and then applying a turning or rotating motion to lock the shield in place.

The UltiCare Safety Insulin Syringes will be available in a range of needle gauges and lengths encompassed by the predicate devices.

**Testing:**

The UltiCare Safety Insulin Syringes 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 Insulin Syringes to the predicate devices.

Performance Testing:

The UltiCare Safety Insulin Syringes have been designed and successfully tested to meet the applicable requirements outlined in ISO 7864, ISO 8537, and ISO 9626.

Biocompatibility Testing:

The new UltiCare Safety Insulin Syringe devices use the exact same materials, dyes/inks, manufacturing process, adhesives, and sterilization process/cycle as the previously cleared UltiCare Safety Syringes (K080600), with the exception of the orange colorant of the needle cap, and therefore additional biocompatibility testing to ISO 10993 standards is not required.

Sterilization and Shelf-life Testing:

Sterilization of the UltiCare Safety Insulin 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.

Clinical Data:

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

**Substantial Equivalence:**

The vast similarities of the UltiCare Safety Insulin Syringes to the predicate devices support the substantial equivalence in intended use, function and basic composition. The non-clinical testing to voluntary standards and applicable FDA guidances provide additional evidence the UltiCare Insulin Syringes are substantially equivalent to the predicate devices in terms of safety, efficacy, and performance.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ulti- Med International, Incorporated
C/O Ms. Mary Beth Henderson
Regulatory & Clinical Research Institute, Incorporated
5353 Wayzata Boulevard, Suite 505
Minneapolis, Minnesota 55416

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Re: K103011
Trade/Device Name: UltiMed UltiCare™ Safety Insulin Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG, FMF, FMI
Dated: January 20, 2011
Received: January 21, 2011

Dear Ms. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# 4.0 INDICATIONS FOR USE STATEMENT

**510(k) Number:** To be determined. (K103011)

**Device Name:** UltiMed UltiCare™ Safety Insulin Syringe

**Intended Use:** The UltiCare Safety Insulin Syringe is intended to inject U-100 insulin into the body. The safety mechanism aids in the prevention of needle stick injuries.

| | | |
|---|---|---|
| Prescription Use: **NO** | AND/OR | Over-the-Counter Use: **YES** |
| (Part 21 CFR 801 Subpart D) | | (21 CFR 801 Subpart C) |

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

2/2/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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