K062702

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NOV 30 2006

510(k) Summary

Submitter
Ulti Med Inc.
287 East Sixth Street
St. Paul, Minnesota
Contact Person: Thomas E. Erickson
Telephone: (651) 291-7909
Fax: (651) 291-7074

Date Prepared
October 10, 2006

Name of Device

Common Name:	Disposable syringes and needles, insulin syringes
Proprietary Name:	UltiCare™ Disposable Syringes and Needles and Insulin Syringes (numerous sizes and combinations varying between the smallest 0.3cc x 31G x 5/16" and the largest 3.0cc x 22G x 1.5")
Classification Name:	Piston Syringe, Hypodermic single lumen needles
Regulation:	880.5860, 880.5570
Class:	Class II
Product Code:	FMF/FMI

Predicate Devices
The UltiCare Disposable Syringes and Needles are substantially equivalent in intended use, function and basic composition to the currently marketed UltiCare Low Dead Space Disposable Syringe (1 ml/cc x 22 G x 1.5"), K994230, and to the UltiCare Disposable Syringe (3 ml/cc, 22 G x 1.5"), K033794.

The Insulin Syringes are substantially equivalent in intended use, function and basic composition to the currently marketed Becton Dickinson BD Insulin Syringes – Ultra-Fine™ and Ultra-Fine™ II, K024112.

Device Description
The UltiCare Disposable Syringes and Needles and Insulin Syringes are standard piston type syringes with permanently attached (unibody) needles. They are sterile, single-use, disposable piston syringes consisting of a syringe barrel, a plunger rod, and a hypodermic single lumen needle. The UltiCare Disposable Syringes and Insulin Syringes are non-toxic and non-pyrogenic, and are available in a variety of combinations of syringe sizes (0.3 to 3.0 cc (ml)), needle sizes (31 to 22 gauge), and needle lengths (5/16" to 1.5").

Intended Use
The UltiCare disposable syringes and needles are used to draw a quantity of pharmaceutical from its container and allow administration of the pharmaceutical directly to the patient. As an alternative use the product will allow administration of the pharmaceutical to the patient via an intravenous port, heparin lock, or saline lock.

The Insulin Syringes are intended for subcutaneous injection of U-100 insulin.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 21 2007

Ulti Med, Incorporated
C/O Ms. Carole Stamp
Regulatory and Clinical Research Institute, Incorporated
5353 Wayzata Boulevard, Suite 505
Minneapolis, Minnesota 55416-1334

Re: K062702
Trade/Device Name: Insulin Syringes, UltiCare™ Disposable Syringes and Needles
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF, FMI
Dated: September 8, 2006
Received: September 11, 2006

Dear Ms. Stamp

This letter corrects our substantially equivalent letter of November 29, 2006.

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 (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.

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.

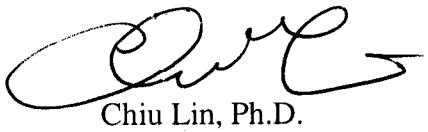
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

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); 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.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 http://www.fda.gov/cdrh/organiz.html#OC for OC organization structure). Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number: K062702

Device Name: Insulin Syringes

Indications For Use:

The Insulin Syringes (0.3 to 1.0 cc) are intended for subcutaneous injection of U-100 insulin.

Prescription Use _____ AND/OR Over-The-Counter Use **X**
(21 CFR 801.Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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Indications for Use

510(k) Number: K062702

Device Name: UltiCare™ Disposable Syringes and Needles

Indications For Use:

The UltiCare disposable syringes and needles (0.3 to 3.0 cc) are used to draw a quantity of pharmaceutical from its container and allow administration of the pharmaceutical directly to the patient. As an alternative use the product will allow administration of the pharmaceutical to the patient via an intravenous port, heparin lock, or saline lock.

Prescription Use __X__ AND/OR (21 CFR 801.Subpart D)

Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

11/28/2006

Urology, General Hospital
Devices

K062702