K033794

Confidential

DEC 3 0 2003

510(k) Summary

Submitter
Ulti Med Inc.
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Date Prepared
04 December 2003

Name of Device

Common Name:	Disposable Syringe
Proprietary Name:	UltiCare™ Disposable Syringe 3 ml/cc
Classification Name:	Piston Syringe
Regulation:	880.5860
Class:	Class II
Product Code:	FMF/FMI

Predicate Devices
The UltiCare 3 ml Disposable Syringe is substantially equivalent in intended use, function and basic composition to the currently marketed Ulti Med UltiCare 1 ml Disposable Syringe, K994230, and to the Becton Dickinson Medsaver™ Syringe, K941095.

Device Description
The UltiCare 3 ml Disposable Syringe is a standard piston type hypodermic syringe, with a black colored protective needle cap.

This device is a sterile, single-use, disposable piston syringe with permanently affixed hypodermic single lumen needle. This device is a sterile, single use, disposable piston syringe with permanently affixed hypodermic single lumen needle. The UltiCare 3 ml Disposable Syringe consists of a syringe barrel, a plunger rod, and a hypodermic single lumen needle permanently bonded to the tip of the syringe with epoxy.

The UltiCare 3 ml Disposable Syringe is available in a 3.0 cc syringe capacity with a 22 GAUGE x 1½" hypodermic single lumen needle.

Intended Use
The UltiCare Disposable Syringe is 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.

Technological Characteristics
The only design change being incorporated into current UltiCare 3 ml Disposable Syringe compared to currently marketed UltiCare 1 ml Disposable Syringe is the syringe capacity and corresponding dimensional changes, and minimal material component changes. All other aspects are identical to the currently marketed

UltiCare Disposable Syringe. UltiCare Disposable Syringes meet the following standards:

ISO 8537, Sterile, Singe-Use Syringes, with or without Needle, for Insulin
ISO 9626, Stainless Steel Needle Tubing for Manufacture of Medical Devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 3 0 2003

Ulti Med, Incorporated
C/O Ms. Ellen G. Redding, MSN
Regulatory and Clinical Research Institute, Incorporated
Principal Regulatory Advisor
5353 Wayzata Boulevard, Suite 505
Minneapolis, Minnesota 55416-1334

Re: K033794
Trade/Device Name: UltiCare™ Disposable Syringe (3 ml/cc)
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: December 4, 2003
Received: December 5, 2003

Dear Ms. Redding:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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 begin 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 (301) 594-4618. 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 (301) 443-6597 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

Enclosure

Indications for Use

510(k) Number (if known): K033794

Device Name: UltiCare™ Disposable Syringe (3 ml/cc)

Indications for Use:

The UltiCare Disposable Syringe is 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.

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

510(k) Number: K033794

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____

(Per 21 CFR 801.109)