

MAR 24 2000

510(k) Number: K994230
UltiCare Disposable Syringe

510(k) Summary

- 1) The submitter of this submission is:

Ulti Med Inc.
287 E. Sixth Street
St. Paul, MN 55101

The contact person is:

Charles W. Erickson

On this 22nd day of March, 2000.

- 2) The trade name of the device shall be "Ulti Care". The name of the device shall be "Low Dead Space" which is also the common or usual name for this type of device.
- 3) The Ulti Care *Low Dead Space* syringe is substantially equivalent to the Becton Dickinson *MedSaver*TM syringe.
- 4) The device is intended to minimize the consumption of expensive pharmaceuticals by reducing the distance between the calibrated barrel of the syringe and the needle. The device has a permanently attached needle that eliminates the tip and hub of a normal needle/syringe combination. This results in less waste of pharmaceutical and greater efficiency.
- 5) The device will be used with any pharmaceutical that needs to be injected either transdermally or through an intravenous port.
- 6) The intended device has the same technological characteristics as the presently marketed Becton Dickinson *MedSaver*TM using a manually operated piston type hypodermic syringe, injected molded plastic parts, a synthetic latex gasket and permanently attached stainless steel needle.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Charles W. Erickson
UltiMed, Inc.
287 East Sixth Street
St. Paul, Minnesota 55101

Re: K994230
Trade Name: UltiCare Disposable Syringe
Regulatory Class: II
Product Code: FMF
Dated: January 10, 2000
Received: January 14, 2000

Dear Mr. Erickson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of

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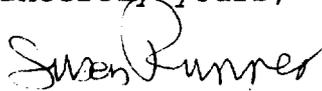
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the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4690. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


for Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K994230
UltiCare Disposable Syringe

Indication For Use

The product is a standard piston type hypodermic syringe. Such device will be used to draw a quantity of pharmaceutical from its container and allow administration of the pharmaceutical directly to the patient. As an alternative use, and which the product will be specifically marketed for, 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 Dental, Infection Control,
and General Hospital Devices
510(k) Number K994230