

510(k) Summary

K081449

**Submitter**

Ulti Med Inc.  
287 East Sixth Street  
St. Paul, Minnesota  
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**Date Prepared**

May 19, 2008

JUN - 3 2008

**Name of Device**

Common Name: Sharps Container  
Proprietary Name: UltiGuard™ Home Insulin Pen Needle Dispenser and Sharps Container  
Classification Name: Hypodermic single lumen needles  
Regulation: 880.5570  
Class: Class II  
Product Code: MMK

**Predicate Devices**

The UltiGuard Home Insulin Pen Needle Dispenser and Sharps Container is substantially equivalent in intended use, function and basic composition to the currently marketed UltiGuard Home Insulin Syringe Dispenser and Sharps Container, K021983.

**Device Description**

The UltiGuard Home Insulin Pen Needle Dispenser and Sharps Container contains 100 insulin pen needles. Pen needles can be removed from the dispenser as needed, and used pen needles can be removed and deposited back into the top of the container for safe storage. When all 100 pen needles have been used and discarded into the container, the container is disposed according to local regulations. The disposable pen needles and UltiGuard container are intended for single use only.

**Intended Use**

The UltiGuard Home Insulin Pen Needle Dispenser and Sharps Container by Ulti Med Inc. is intended to be used to transport, store and dispense insulin pen needles in the home. After use the used pen needle can be placed back into the container for safe storage and eventual disposal according to local regulations.

**Technological Characteristics**

The UltiGuard Home Insulin Pen Needle Dispenser and Sharps Container has similar technological characteristics to the currently marketed predicate device listed above. The UltiGuard Home Insulin Pen Needle Dispenser and Sharps Container meets the following standards:

BS 7320 (1990), Specifications for Sharps Containers  
ASTM F2132 (2001), Puncture Resistance of Materials Used in Containers for Discarded Medical Needles

**Performance Data (non-clinical or clinical)**

The UltiGuard Home Insulin Pen Needle Dispenser and Sharps Container is substantially equivalent to the predicate device based on the descriptive data, compliance with standards, and indications for use.

**Conclusion**

The technological characteristics and performance data for the UltiGuard Home Insulin Pen Needle Dispenser and Sharps Container demonstrate it is substantially equivalent to the predicate device.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN - 3 2008

Ulti Med Incorporated  
C/O Mr. Mark Job  
Responsible Third Party Official  
Regulatory Technology Services, LLC  
1394 25<sup>th</sup> Street NW  
Buffalo, Minnesota 55313

Re: K081449

Trade/Device Name: UltiGuard™ Home Insulin Pen Needle Dispenser and  
Sharps Container

Regulation Number: 21 CFR 880.5570

Regulation Name: Hypodermic Single Lumen Needle

Regulatory Class: II

Product Code: MMK

Dated: March 27, 2008

Received: May 23, 2008

Dear Mr. Job:

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 (240) 276-0115. 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/industry/support/index.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:** Not assigned

**Device Name:** UltiGuard™ Home Insulin Pen Needle Dispenser and Sharps Container

**Indications For Use:**

The UltiGuard Home Insulin Pen Needle Dispenser and Sharps Container by Ulti Med Inc. is intended to be used to transport, store and dispense insulin pen needles in the home. After use the used pen needle can be placed back into the container for safe storage and eventual disposal according to local regulations.

Prescription Use \_\_\_\_\_  
(21 CFR 801.Subpart D)

AND/OR

Over-The-Counter Use   **X**    
(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 Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

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