

FEB 2 1998



MiniMed Inc.  
Premarket Notification - 510(k)  
Sof-set Ultimate QR infusion set, models 315 and 316

K974103

**Part E. 510(k) Summary**

**Submitter:** MiniMed® Inc. 12744 San Fernando Rd., Sylmar, California 91342.

**Contact:** Don Selvey, Regulatory Affairs (818) 362-5958, 3011; (520) 527-0107 (v/f).

**Name of Device:** MiniMed® Sof-set® Ultimate QR® infusion sets, models 315 and 316.

**Predicate Device:** MiniMed Sof-set QR infusion sets, models 115 and 116.

**Description of the New Device:** The MiniMed Sof-set Ultimate QR infusion sets, models 315 and 316, are infusion administration sets, connecting to a medicine reservoir proximally, and inserted in the subcutaneous tissue of a user distally by means of an introducer needle. The reservoir to which the infusion set attaches proximally is inserted into an external infusion pump, such as the MiniMed 507 insulin pump.

The administration set attaches to the reservoir syringe by means of a female Luer connector, and subcutaneously in the user through an indwelling catheter made of FEP Teflon. The tubing is made of polyvinyl chloride (PVC) with a polyolefin liner. This configuration of PVC and polyolefin has been trademarked by MiniMed as Polyfin.

The 24 gauge indwelling catheter is introduced into the subcutaneous tissue by a removable 26 gauge introducer needle made of 304 stainless steel. The needle, indwelling catheter, and tubing share a common hub. The hub incorporates a winged configuration to facilitate handling of the administration set during insertion and stability following insertion.

On the skin-contact side of the wings, around the Teflon catheter, is an antibacterial dressing. Additionally, an adhesive dressing covers the wings of the administration set, securing the subcutaneous catheter and infusion line to the user.

**Intended Use of the New Device:** The MiniMed Sof-set Ultimate QR is intended for the subcutaneous infusion of medicine, including insulin, from an external infusion pump. The set is not intended nor indicated for use with blood or blood products.

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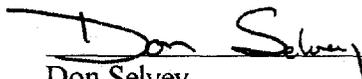
**Comparison of the Technological Features of the New Device and Predicate Device:** The modified devices are substantially similar to the lawfully marketed predicate devices. Both are intended for subcutaneous delivery insulin or other appropriately labeled medicines from an infusion pump to the pump user. Both sets attach proximally to a reservoir by means of a Luer connector, and insert distally into the device user's subcutaneous tissues with a removable stainless steel needle and flexible catheter. Both devices are made of substantially similar materials.

Several differences exist between the new and predicate device:

- 1) changes in the shape/configuration of the hub and wings to be flatter and smoother;
- 2) the indwelling catheter is clear instead of white;
- 3) a change in the adhesive tab to be slightly longer and rotated 90°, facilitating tab removal prior to insertion and use with an auto inserter device;
- 4) a change in the adhesive tape: the infusion set will be secured with IV 3000, a product of Smith & Nephew;
- 5) a change in the polyethylene plastic in the inner layer of the tubing, from low density to a higher density. This has resulted in a more sensitive occlusion alarm, which will be promoted by MiniMed.

These modifications do not affect the safety or effectiveness of the device.

Signed,

  
Don Selvey  
Regulatory Affairs  
MiniMed Inc.

10-27-97  
date

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FEB 2 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Don Selvey  
Regulatory Affairs  
MiniMed® Incorporated  
12744 San Fernando Road  
Sylmar, California 91342

Re: K974163  
Trade Name: MiniMed® Sof-set® Ultimate QR® infusion  
sets, models 315 and 316  
Regulatory Class: II  
Product Code: FPA  
Dated: October 27, 1997  
Received: November 5, 1997

Dear Mr. Selvey:

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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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 premarket notification submission does

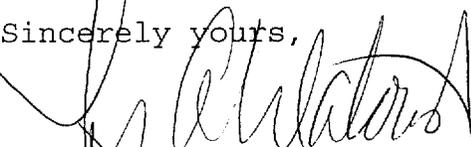
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not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4618. 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,



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

Enclosure

MiniMed Inc.  
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Sof-set Ultimate QR infusion set, models 315 and 316

## INDICATIONS FOR USE

**510(k) Number:**

**Device Name:** MiniMed Sof-set Ultimate QR infusion sets, models 315 and 316.

**Indications for Use:** The MiniMed Sof-set Ultimate QR infusion set is indicated for the subcutaneous delivery of medicine, including insulin, from an external infusion pump.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
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(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K974163

Prescription Use    
(Per 21 CFR 801.109)

or

Over-the-Counter Use \_\_\_\_\_

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