SEP 28 1993

K925632

Attachment 6

Summary of Safety and Effectiveness
Modified Subcutaneous Infusion Set

The subject of this submission is a Subcutaneous Infusion Set intended to inject fluids into, or withdraw fluids from, parts of the body below the skin. A change is being made in the material used to bond the set needle to the tubing. All other set materials and components, as well as set design and intended use, remain the same as the currently marketed set.

The new material has been evaluated for biological compatibility and has been shown to be safe and suitable for its intended use.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

SEP 28 1993

Ms. Marcia Marconi
Director, Regulatory Affairs
Baxter Healthcare Corporation
Route 120 and Wilson Road
Round Lake, Illinois 60073-0490

Re: K925632
Sub-Q-Set® Subcutaneous Infusion Set
Regulatory Class: II
Dated: August 26, 1993
Received: August 27, 1993

Dear Ms. Marconi:

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 to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket 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. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being

approved by FDA. If you desire specific advice on the labeling for your device, please contact the Division of Compliance Operations, Promotion and Advertising Policy Staff (HFZ-326) at (301) 594-4639. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Paul R. Beninger, M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health