K033290

ICU Medical, Inc.

APR 1 2 2004

SUMMARY OF SAFETY AND EFFECTIVENESS
Talon Infusion Set

§807.92(a)(1)

Contact Person	Dale Fairchild Regulatory Manager
Date of Summary Preparation:	October 10,2003

§807.92(a)(2)

Trade Name:	Talon
Common Name:	Infusion Set
Classification Name:	Intravascular administration set (21 CFR 880.5440

§807.92(a)(3)

Legally Marketed Substantially Equivalent Device:	Glucopro Infusion Set

§807.92(a)(4)

Description of Device:	The Talon infusion sets are connected to a medication reservoir proximally (i.e., a syringe that is placed within an infusion pump, such as an insulin pump) and distally inserted into the subcutaneous tissue of the user. The infusion set attaches to the medication reservoir by means of a female luer connector and is inserted into the patient through an introduction

951 Calle Amanecer - San Clemente, CA 92673 • (949) 366-2183 • (800) 824-7890 • Fax (949) 366-8368 • www.icumed.com

cannula. The 26 gauge indwelling catheter is connected to tubing of various lengths. The materials used for the components include: PVC/polyethylene; polyvinyl chloride; polytetrafluorethylene; stainless steel; polycarbonate; polypropylene; and, trace amounts of silicone as a lubricant. All of these materials are typically used in medical devices.

§807.92(a)(5)

Intended Use:

The Talon infusion set is an administration infusion set intended to be used for subcutaneous infusion of medicine solutions, such as insulin, from an external infusion pump.

§807.92(a)(6)

Comparison of Technical Characteristics:

The Talon infusion set is similar to legally marketed devices with the same intended use and design.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 2 2004

Mr. Dale Fairchild
Regulatory Affairs Manager
ICU Medical, Incorporated
951 Calle Amanecer
San Clemente, California 92673

Re: K033290
Trade/Device Name: Talon Insulin Pump Infusion Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: February 4, 2004
Received: February 5, 2004

Dear Mr. Fairchild:

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.

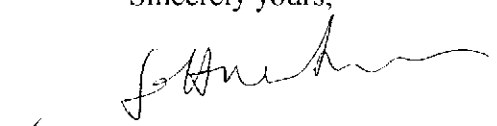
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



for, 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): K033290

Device Name: Talon Infusion Set

Indications For Use: The Talon insulin pump infusion set is an administration infusion set intended to be used for subcutaneous infusion of medicine solutions, such as insulin, from an external infusion pump

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

Jean Raveau for ADW 4/8/04
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K033290