JUL 26 1999

510(k) Summary

Luer Access Injection Site

K984060

Submitted by:

Mary Ellen Snyder
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I.V. Systems Division
Rt. 120 and Wilson Road
Round Lake, IL 60073

Date Prepared:

November 12, 1998

Proposed Device:

Luer Access Injection Site

Predicate Device:

ICU Medical Inc. Clave™ Needleless Connector

Proposed Device Description:

The subject of this submission is a luer access injection site which will be marketed as a stand-alone device for use as a heparin lock and will also be incorporated into currently marketed solution sets. The proposed injection site consists of a pre-slit synthetic polyisoprene septum and a polyester housing.

Statement of Intended Use

The proposed luer access injection site and sets incorporating it will be used with a vascular access device for fluid administration and blood sampling. The luer access injection site can be connected to male luer adapters e.g., syringes or sets, to allow needleless access to the vascular path. This device is for use as part of a program to reduce needle-stick injuries and the associated transmission of blood borne pathogens.

Summary of Technological Characteristics of New Device to Predicate Devices

The proposed luer access injection site is similar to the currently marketed ICU Medical Inc. Clave™ Needleless Connector, cleared under K970855 and K915571. Both devices are injection ports activated by male luer connectors to allow needleless access to the fluid or vascular path. One key difference between the proposed luer access injection site and the Clave™ Connector is the method of operation. The proposed injection site contains a preslit septum which is opened with insertion of a male luer adapter. The septum reseals when the male luer is removed. The Clave™ Connector contains a silicone seal which is depressed, with insertion of the male luer, below the openings of an internal plastic conduit, permitting fluid flow. With disconnection of the luer, the silicone seal springs back above the conduit, resealing it and stopping fluid flow. There are no new materials involved in the proposed device. All solution contact materials to be used in the proposed device are identical to materials used in legally marketed devices under comparable conditions of use.

Discussion of Nonclinical Tests and Referenced Studies Reported in Published Literature

Performance testing of the proposed luer access injection site has been conducted including microbiological evaluations. A description of the testing along with test results has been provided. All data indicate that the proposed device meets or exceeds all functional and microbiological requirements and thus support its suitability for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Mary Ellen Snyder
Senior Manager,
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Baxter Healthcare Corporation
I.V. Systems Division
Route 120 and Wilson Road
Round Lake, Illinois 60073-0490

Re: K984060
Trade Name: Luer Access Injection Site
Regulatory Class: II
Product Code: FPA
Dated: June 23, 1999
Received: June 24, 1999

Dear Ms. Snyder:

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 (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. 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 premarket notification submission does 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) 594-4692. 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

Indication for Use

510(k) Number: Not Available

Device Name: Luer Access Injection Site

Indication for Use: The proposed luer access injection site and sets incorporating it will be used with a vascular access device for fluid administration and blood sampling. The luer access injection site can be connected to male luer adapters, (e.g., syringes or sets) to allow needleless access to the vascular path. This device is for use as part of a program to reduce needle-stick injuries and the associated transmission of blood borne pathogens.

Nick Hilliard for Pat Cucinotti

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K984060

Prescription Use ✓
(Per 21 CFR 801.109)