K981318

510(k) SUMMARY

Dual Luer Lock Cap

Submitted by:

Mary Ellen Snyder
Baxter Healthcare Corporation
I.V. Systems Division
Rte. 120 and Wilson Road
Round Lake, IL 60073

Date Prepared:
April 9, 1998

Proposed Device:
Dual Luer Lock Cap

Predicate Device:
Medex Male/Female Luer Lock Plug
B. Braun Blue Cap Dual Function Lock Lock Plug
Abbott Male/Female Sterile Cap

Proposed Device Description:

The subject of this submission is a sterile Dual Luer Lock Cap which will be used to cover male or female luer ports on medical devices. The proposed Dual Luer Lock Cap will replace the existing port cap on a number of currently marketed Baxter devices such as sets, stopcocks and manifolds. It will also be sold individually as a replacement cap to cover an open luer port after it has been accessed and is no longer in use. The Dual Luer Lock Cap consists of an integrated design with a male luer lock connection on one end and a female luer lock connection on the other end.

Statement of Intended Use:

The Dual Luer Lock Cap is intended for use as a cap for male or female luer ports on medical devices such as manifolds, stopcocks or sets.

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Summary of Technological Characteristics of New Device to Predicate Devices

The proposed Dual Luer Lock Cap is similar in design characteristics to several other marketed sterile replacement caps which feature a dual male/female luer connection. These include the Medex Male/Female Luer Lock Plug, the B. Braun Blue Cap Dual Function Lock Lock Plug and the Abbott Male/Female Sterile Cap. It is also similar to the existing port cap on Baxter's MultiPort Manifold.

There are no new materials involved in the proposed device. It is comprised of the same material used to fabricate the current port protector on Baxter's marketed MultiPort Manifold.

Discussion of Nonclinical Tests and Referenced Studies Reported in Published Literature

Data regarding the functional performance of the proposed Dual Luer Lock Cap have been generated. A description of the functional testing along with test results has been provided. The data indicate that the proposed cap meets or exceed all functional requirements and support its suitability for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 22 1998

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

Re: K981318
Trade Name: Dual Luer Lock Cap
Regulatory Class: II
Product Code: FPA
Dated: April 9, 1998
Received: April 10, 1998

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

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510(k) Number: Not Available

Device Name: Dual Luer Lock Cap

Indication for Use:

Baxter's Dual Luer Lock Cap is intended for use as a cap for male or female luer ports on medical devices such as manifolds, stopcocks or sets.

Patricia Cicenti
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K981318

Prescription Use _____
(Per 21 CFR 801.109)