

**BECTON DICKINSON PHARMACEUTICAL SYSTEMS**

MAY 29 1998

**510(k) SUMMARY**

Date of preparation: December 11, 1997

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA 1990 and 21 CFR 807.92.

A. REASON FOR 510(k): Introduction of a new product.

B. NAME OF DEVICE:

- *Proprietary name* : B-D® Auto-Injector
  - *Classification name* : Syringe needle introducer
  - *Common or usual name* : auto-injector
  - *Class* : Class II
- Classification panel:* General Hospital, Panel 80;  
Regulation Number 21 C.F.R § 880.6920

D. ESTABLISHMENT REGISTRATION NUMBER: 8023072

E. SUBMITTER'S NAME AND ADDRESS:

Becton Dickinson and Company  
Pharmaceutical Systems Division  
1 Becton Drive  
Franklin Lakes, New Jersey 07417-1886

Contact person: Michael Gross, Ph.D.  
Tel : 201-847-5930  
Fax : 201-847-4854

F. MANUFACTURING FACILITIES:

Becton Dickinson France SA  
Pharmaceutical Systems Division  
BP4 38800 Le Pont-de-Claix, France  
Tel : 33 4 76 68 36 36  
Fax : 33 4 76 68 37 88  
FDA Device Establishment Registration Number: 8023072

**G. PERFORMANCE STANDARD(S) :**

No performance standards applicable to syringe needle introducers or similar products have been promulgated under Section 514 of the Food, Drug and Cosmetic Act. The product has been tested in terms of biocompatibility and conforms to ISO standard 10993-1.

**H. DEVICE DESCRIPTION AND INTENDED USE :**

The intended use is to provide to patients a safe, simple and easy subcutaneous injection system in order to self-administer injectable drugs or biologics.

The B-D<sup>®</sup> Auto-Injector is a syringe needle introducer. Syringe needle introducers are devices that use a spring-loaded mechanism to perform an injection at a predetermined depth with an hypodermic needle.

The B-D<sup>®</sup> Auto-Injector is intended to be used exclusively with drugs or biologics packaged in the HYPAK<sup>®</sup> cartridge system which contains a HYPAK<sup>®</sup> prefilled syringe. It is intended for use only with FDA approved drugs or biologics in dosages indicated in their labeling.

The B-D<sup>®</sup> Auto-Injector is made of molded plastic parts and springs. Similar technology characteristics are found in various commercially marketed auto-injectors which operate on the same principle.

**I. SUBSTANTIAL EQUIVALENCE**

The BD Auto-Injector is substantially equivalent to **Ulster Scientific Inc.'s Diamatic<sup>™</sup> auto-injector, (K860284)** which was cleared by FDA in April 1986.

*The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug, and Cosmetic Act, as amended and as supplied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statement related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the court.*

**[END OF SUMMARY]**



MAY 29 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Dr. Michael Gross, Ph.D.  
Director, Corporate Regulatory Affairs  
Becton Dickinson and Company  
Pharmaceutical Systems Division  
One Becton Drive  
Franklin Lakes, New Jersey 07417-1886

Re: K974678  
Trade Name: B-D® Auto-Injector  
Regulatory Class: II  
Product Code: KZH  
Dated: April 8, 1998  
Received: April 9, 1998

Dear Dr. Gross:

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 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). 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.

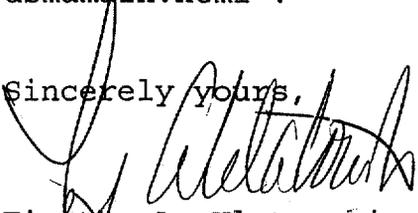
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, 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 pre-market 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" (21CFR 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/dsma/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

510(k) Number (if known):

Device Name:

Indications for Use:

The B-D® Auto-Injector is indicated for assisting the injection of a fixed dose of an approved drug or biologic packaged in a HYPAK® Cartridge component which contains a HYPAK® syringe prefilled with the drug or biologic.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_ OR Over-The-Counter Use \_\_\_\_\_

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

*Patricia Crossin*

(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number       K974678