

510(k) Summary

Prepared: May 20, 1997

Submitted by:

OCT - 1 1997

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B&D Corp.
14 Michael Drive
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Device Name

Classification Name:	Activated Whole Blood Clotting Time Test
Common/Usual Name:	Activated Whole Blood Clotting Time Test
Proprietary Name:	B&D Activated Clotting Time (ACT) test tubes BD-C101 (diatomaceous earth) and BD-K101(kaolin)

Predicate Device

International Technidyne Corp. FTCA510 (diatomaceous earth) - a preamendment device, marketed since 1970, and KACT (K913861).

Device Description

Activated coagulation time (ACT) test tubes are used for monitoring heparin and aprotinin anticoagulation during coronary bypass surgery, coronary angioplasty and other medical/surgical procedures. These test tubes contain a clotting activator (either diatomaceous earth or kaolin), flip-top cap and a plastic insert that retains the magnet at the bottom of the test tube. Fresh whole blood is added to the test tube, it is mixed and placed into an instrument that is designed to display the activated clotting time (ACT) when the clotting is formed. This activated clotting time (ACT) timing indicates to physicians if the patient needs any anticoagulation adjustments.

Statement of Intended Use

The sole intended use of this product is to monitor heparin and aprotinin anticoagulation in whole blood. Typically, heparin and aprotinin therapy are commonly used during coronary bypass surgery, coronary angioplasty and several other medical/surgical procedures.

Summary of Technological Characteristics

Both the predicate device (FTCA510) and BD-C101 contain diatomaceous earth as the activator. Composition of the test tubes are glass test tubes 13 x 100 mm, polyethylene flip-top caps and inserts, and ceramic magnets.

Both the predicate device (KACT) and BD-K101 contain kaolin as the activator. Composition of the test tubes are glass tubes 13 x 100 mm, polyethylene flip-top caps and inserts, and ceramic magnets.

Summary of Performance Data

To establish equivalence, the diatomaceous earth activated tubes (FTCA510 and BD-101) were tested two ways. First, clotting times were compared for fresh whole blood with four different heparin concentrations, as well as a baseline. The Celite® test tubes were run on Hemochron® 8000 according to the manufacturers instructions (International Technidyne Corp.). The correlation coefficient was 0.999.

Second, clotting time was tested using Hemochron Quality Control Plasma (CPL2) at Normal and Abnormal levels. All values and their averages were centered around the midrange specified for the Quality Control Plasma.

The kaolin activated tubes (KACT and BD-K101) were tested similarly with different levels of heparin. The correlation coefficient was 0.999.

Clotting time for the kaolin tubes using Hemochron Quality Control Plasma (CPL2) at Normal and Abnormal was also determined. All values and their averages were centered around the midrange specified for the Quality Control Plasma.

It was concluded that Hemochron FTCA510 and BD-C101 are equivalent in measuring the clotting time of fresh whole blood, fresh whole blood with different levels of heparin, and Hemochron Quality Control Plasma at Normal and Abnormal levels.

It was concluded that Hemochron KACT and BD-K101 are equivalent in measuring the clotting time of fresh whole blood, fresh whole blood with different levels of heparin, and Hemochron Quality Control Plasma at Normal and Abnormal levels.



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Hardeep Dhaliwal
. President
B&D Corporation
14 Michael Drive
Metuchen, New Jersey 08840

OCT - 1 1997

Re: K971935
B&D Activated Clotting Time Test Tubes BD-C101
Regulatory Class: II
Product Code: JBP
Dated: July 17, 1997
Received: July 23, 1997

Dear Mr. Dhaliwal:

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.

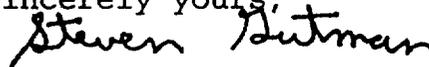
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 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.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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) 594-4588. 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,



Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K971935

Device Name: B&D Activated Clotting Time Test Tubes - BD-C101 (Celite) & BD-K101 (Kaoli)

Indications For Use:

Request 1. *Modify the intended use to reflect the correct function of aprotinin.*

Response: page 6 of the submission has been modified as follows:

Intended use:

B&D Activated Clotting Time (ACT) test tubes are intended for use in monitoring anticoagulation effects of heparin. Heparin is commonly used during coronary bypass surgery, coronary angioplasty and several other medical/surgical procedures in order to prevent thrombus formation. B&D Kaolin ACT test tubes (BD-K101) are not sensitive to aprotinin, and are the appropriate ACT test tubes to monitor heparin in patients treated with the moderate levels of protease inhibitor, aprotinin (up to 180 KIU/mL).

B&D ACT test tubes are for whole blood, in-vitro diagnostic use only.

B&D ACT test tubes are to be used with several whole blood ACT analyzers currently available, such as Hemochron® ACT analyzers Model numbers: 400, 401, 800, 801 and 8000.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K971935

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

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