K093972

510(k) Summary Of Safety and Effectiveness

JAN 21 2010

I. General Information

This Summary of Safety and Effectiveness information is being submitted in accordance with the requirements of the SMDA of 1990 and 21 § 807.92

Establishment:

- Address: Becton, Dickinson and Company
  BD Diagnostics, Preanalytical Systems
  1 Becton Drive
  Franklin Lakes, NJ 07417-1885
- Registration Number: 2243072
- Contact Person: Julie Tom Wing
  Regulatory Affairs Specialist
  Telephone no.: 201-847-4260
  Fax No. 201-847-4858
- Date of Summary: December 23, 2009

Device

- Trade Name: BD Microtainer® MAP Microtube for Automated Process
- Classification Name: Tubes, Vials, Systems, Serum Separators, Blood Collection
- Classification: Class II
- Performance Standards: None Established under 514 of the Food, Drug and Cosmetic Act

II. Safety and Effectiveness Information Supporting Substantial Equivalence

- Device Description

BD Microtainer® MAP Microtube for Automated Process consists of a plastic reservoir and a lavender cap indicating the presence of K_2EDTA. The interior surface of the reservoir is spray-coated with K_2EDTA solution, which is then dried. The upper edge of the reservoir serves as a collector for blood specimen. The plastic reservoir is a one piece design – reservoir and extender, which were previously two separate components in the predicate device (K940905).

The integrated extender gives the tube an external dimension of a standard tube (13x75mm), while maintaining the same internal characteristics for low specimen volume range and K_2EDTA blood to additive ratio as the predicate. The lavender cap features a penetrable septum.

These integrated features: one piece reservoir/extender and penetrable cap adapts the tube for compatibility with high throughput hematology instruments. Once the blood specimen is collected and mixed adequately, there is no longer a need to remove the cap, transfer the sample to a suitable container or add an additional component to fit tube racks.

BD MAP can be directly processed on high throughput hematology instruments. Markings on the reservoir indicate a blood specimen fill range of 250µL to 500µL. There is also a tube marking for specimen fill (375µL) when the tube is processed in automated mode.

While BD MAP is adaptable to automated processing; the tube remains compatible with automated instruments when processed in the manual mode.

- Intended Use

BD Microtainer® MAP Microtube for Automated Process with K_2 EDTA is used to collect, anticoagulate, transport and store skin puncture blood specimens for measurement of the following hematology parameters:

White Blood Cells (WBC), Red Blood Cells (RBC), Hemoglobin (HgB), Hematocrit (HCT), Mean corpuscular volume (MCV), Mean corpuscular hemoglobin (MCH), Mean corpuscular hemoglobin concentration (MCHC), Platelets, 5-part White Blood Cell (WBC) differentials (Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils), Reticulocytes and Whole Blood Lead testing.

- Synopsis of Performance Study Results

Mechanical, simulated use and clinical testing were performed to demonstrate the device's safety and effectiveness.

III. Predicate Device Summary Table

- Substantial Equivalence

Based on comparison of the device features, materials, intended use and performance, BD Microtainer® MAP Microtube for Automated Process with K_2EDTA is shown to be substantially equivalent to the commercially available predicate device indicated in the table below.

The predicate device, K number, and clearance date are also identified in the table below.

Manufacturer	Predicate Device	K-Number	Clearance Date
Becton, Dickinson and Company	BD Microtainer® K_2EDTA tube with Microgard™ Closure and Extender	K940905	August 02, 1994

Julie Tom Wing
Julie Tom Wing
Regulatory Affairs Specialist
Becton, Dickinson and Company
BD Diagnostics, Preanalytical Systems

12/22/2009
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center-WO66-G609
Silver Spring, MD 20993-0002

JAN 21 2010

Becton, Dickinson & Co.
BD Diagnostics, Preanalytical
c/o Ms. Julie T. Wing
Regulatory Affairs Specialist
1 Becton Drive, MC 300
Franklin Lakes, NJ 07417-1880

Re: k093972
Trade/Device Name: BD Microtainer® MAP Microtube for Automated Process
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: JKA
Dated: January 15, 2010
Received: January 19, 2010

Dear Ms. Wing:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093972

Device Name: BD Microtainer® MAP Microtube for Automated Process

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Prescription Use X 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 In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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