

JUL 12 2010

 陽普醫療 IMPROVE MEDICAL	Guangzhou Improve Medical Instruments Co., Ltd. 510 (K) Submission for IMPROVACUTER® Evacuated Blood Collection Tubes
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Attachment V 510(K) Summary

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

The Assigned 510(k) Number is: K093910

Date Prepared: 05 JUL 2010

1. Sponsor Information

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2. Submission Correspondent

Ms. Diana Hong, General Manager
Shanghai Mid-Link Business Consulting Co., Ltd
Suite 5D, No.19, Zhongshan Road (S-2)
Shanghai, 200030, China.



Guangzhou Improve Medical Instruments Co., Ltd.

510 (K) Submission for IMPROVACUTER[®] Evacuated Blood Collection Tubes

3. Proposed Device Identification

Device Name: IMPROVACUTER[®] Gel & Clot Activator Tube

Specifications: 13 x 75 mm / 13 x 100 mm

Draw Volume: 3-5 ml for both specifications

Classification Name

Classification: Class II

Product Code: JKA

Regulation Number: 21 CFR. 862.1675

4. Device Description

The IMPROVACUTER[®] Gel & Clot Activator Tube is sterile, plastic, evacuated blood collection tube. The tube consists of (1) a closure assembly, (2) a silica clot activator, (3) a Barrier Gel, and (4) a plastic tube. The specimens are used for clinical laboratory assays involving the use of patient serum.

5. Intended Use

IMPROVACUTER Gel & Clot Activator Tube is a single use tube used to collect, transport, separate, and process venous blood specimens to obtain serum for clinical chemistry and immunology assays. It is used in settings where a venous blood sample is collected by a trained healthcare worker. For in vitro diagnostic use.

6. Predicate Device Identification

BD Vacutainer[®] Gel & Clot Activator Tube (plastic)

510(k) Number: K023075.



7. Substantial Equivalence

Based on a comparison of the features, materials and intended use, the IMPROVACUTER[®] Gel & Clot Activator Tube are substantially equivalence to the commercially available predicate devices. The only difference between the predicate and the IMPROVACUTER[®] Gel & Clot Activator Tube is the performance claim not for Therapeutic Drug Monitoring (TDM). SE comparison information is presented below:

Table 7-1 Similarities and differences table between your predicate and your candidate devices

ITEM	Proposed Device IMPROVACUTER [®] Gel & Clot Activator Tube	Predicate Device BD Vacutainer [®] Gel & Clot Activator Tube (plastic) K023075
Intended Use	IMPROVACUTER Gel & Clot Activator Tube is a single use tube used to collect, transport, separate, and process venous blood specimens to obtain serum for clinical chemistry and immunology assays. It is used in settings where a venous blood sample is collected by a trained healthcare worker. For in vitro diagnostic use.	The BD Vacutainer [®] Tube is a evacuated blood collection tube that provides a means of collecting, transporting, separating, and processing blood in a closed tube. Blood collected in a Vacutainer [®] Tube is primarily used for clinical laboratory testing in chemistry using patient serum, but may be used for other assays requiring serum specimens as determined by the laboratory. In addition, the Vacutainer [®] Tube is compatible with many commonly used therapeutic drugs therefore suitable for therapeutic drug monitoring (TDM).
Tube Dimension	13 x 75 mm 13 x 100 mm	13 x 75 mm
Draw Volume	3-5 ml	3.5 ml
Closure	Conventional Rubber Closure	SAME
Clot Activator	Silica	SAME
Tube Shelf Life	12 months	SAME
Sterility	Sterilized	SAME
Package	Plastic film barrier bag in cardboard shelf carton.	SAME

8. Synopsis of Test Methods and Results

Method Comparison Studies

Clinical evaluations were performed to determine the safety and efficiency of the IMPROVACUTER[®] Gel & Clot Activator Tube. The devices were compared to the predicate BD Vacutainer[®] tubes in total 28 chemistry assays and 13 Immunology assays. The results of the clinical evaluation demonstrated that the IMPROVACUTER[®] Gel & Clot Activator Tube provide clinically equivalent chemistry analyte results when compared to the BD Vacutainer[®] tubes.

All comparison studies results demonstrate that there are no major differences between IMPROVACUTER[®] tubes and BD Vacutainer[®] tubes.

Stability Studies

Studies were conducted to compare fresh specimens, 24 hours and 48 hours stored both at 2-8°C and at 22-25°C. All results showed no significant different from BD Vacutainer[®] stored under the same condition.

Analyte stability testing has been conducted for all the analytes listed. Stability for 24 hours at room temperature and refrigerated temperature has been demonstrated for all the analytes except TBIL. TBIL is stable at room temperature for up to 20 hours.

All comparison studies results demonstrate that there are no major differences between IMPROVACUTER[®] tubes and BD Vacutainer[®] tubes.

Shelf- life Studies

The shelf life studies are to research whether the IMPROVACUTER[®] Gel & Clot Activator Tube have significant difference from the ones which had just been manufactured. All results showed no significant different from these.

All comparison studies results demonstrate that there are no major differences between IMPROVACUTER[®] tubes and BD Vacutainer[®] tubes.

Same-Lot Repeatability Study

This test is intended to test IMPROVACUTER[®] Gel & Clot Activator Tube, whose lots are the same to those of products used in Method Comparison Study. Compare the test results with those of Method Comparison Study to determine whether there are major differences.

All comparison studies results demonstrate that there are no major differences between IMPROVACUTER® tubes and BD Vacutainer® tubes.

Lot-to-Lot Reproducibility Study

Select 2 lots from both materials of normally produced IMPROVACUTER® Gel & Clot Activator Tube, and compare the test results with those of Method Comparison Study to determine whether there are major differences.

All comparison studies results demonstrate that there are no major differences between IMPROVACUTER® tubes and BD Vacutainer® tubes.

Standard/ Guidance Document Referenced

- CLSI Guideline, EP9-A2: Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline Second edition.
- CLSI H18-A3: Procedures for the Handling and Processing of Blood Specimens; Approved Guideline
- CLSI H1-A5: Evacuated Tubes and Additives for Blood Specimen Collection, Approved Standard –Fifth Edition
- CLSI H3-A6: Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture, Approved Standard –Fifth Edition
- ANSI/AAMI/ISO 11137: Sterilization of Health Care Products - Requirements for Validation and Routine Control - Radiation Sterilization



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Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

JUL 12 2010

Re: k093910
Trade Name: IMPROVACUTER® Gel & Clot Activator Tube
Regulation Number: 21 CFR §862.1675
Regulation Name: Blood specimen collection devices
Regulatory Class: Class II
Product Codes: JKA
Dated: July 05, 2010
Received: July 07, 2010

Dear Ms. Hong:

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 either class II (Special Controls) or class III (PMA), 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).

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), 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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure



Guangzhou Improve Medical Instruments Co., Ltd.

510 (K) Submission for IMPROVACUTER® Evacuated Blood Collection Tubes

Attachment I Indication for Use

510(k) Number: K093910

Device Name: IMPROVACUTER® Gel & Clot Activator Tube

Indication for Use:

IMPROVACUTER Gel & Clot Activator Tube is a single use tube used to collect, transport, separate, and process venous blood specimens to obtain serum for clinical chemistry and immunology assays. It is used in settings where a venous blood sample is collected by a trained healthcare worker.

For in vitro diagnostic use.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

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Office of In Vitro Diagnostic
Device Evaluation and Safety

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