JUN 15 2006

K060364

TECO DIAGNOSTICS

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510 K Summary
Teco Vacu Lab. Plain Tube & Vacu Lab Gel & Clot Activator Tube

Device Name

The device trade names and common/classifications name are:

Device Trade Name	Common/Classification Name
Teco Blood Specimen Collection Devices: Vacu lab Plain Tube Vacu Lab Gel & Clot Activator Tube	Tubes, Vials, Systems, Serum Separators, Blood Collection

Address and Registration

The address and registration number of the manufacturer site for Teco Blood Specimen Collection Devices.

TECO Diagnostics
1268 N. Lakeview Ave.
Anaheim, CA 92807, U.S.A.
FDA Registration # 1832216

Contact Person: Jian Vaeches
Prepared Date: 03/12/2006

Device Class

Teco Blood Specimen Collection Devices have been classified as Class II with Product Code JKA"in vitro" diagnostics devices having the classification number: 21 CFR. 862.1675. This is the description available from the classification names listed in the " CDRH Home Page- Listing Database."

Labeling and Intended Use

Draft labels and Instructions for use can be found in appendix A.

Intended Use
Teco Blood Specimen Collection Devices: Vacu lab Plain Tube and Vacu Lab Gel & Clot Activator Tube provide a means for collection, processing and transportation of blood in a closed system. Blood collected in these

tubes is primarily used for clinical laboratory chemistry assays, but may be used for other assays requiring serum specimens as determined by the laboratory.

Device Description

The Teco Blood Collection Devices include: Vacu Lab Plain Tube; Vacu Lab Gel & Clot Activator Tube;

1. The Vacu Lab Plain Tube is sterile, plastic, evacuated blood collection tube. The tube consists of (1) a closure assembly, (2) a silica clot activator, and (3) a silicone surfactant coated plastic tube. The specimens are used for clinical laboratory assays involving the use of patient serum.
2. The Vacu Lab 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 silicone surfactant coated plastic tube. The specimens are used for clinical laboratory assays involving the use of patient serum.

Method Comparison of Vacu Lab Plain Tube; Vacu Lab Gel & Clot Activator Tube to BD Vacutainer ™ Plus SST ™ Tube following the guidelines of NCCLS Guideline EP9-A2 was conducted.

Substantial Equivalence

Base on a comparison of the device features, materials and intended use, the Teco Blood Specimen Collection Device: Vacu lab Plain Tube and Vacu Lab Gel & Clot Activator Tube is substantially equivalent to the predicate devices.
The predicate device is BD Vacutainer ™ Plus SST ™ Tube
The 510 (K) approval letter is provided in Appendix I.
510(K) #: K023075
Approval Date: 11-25-2002

Synopsis of Test Methods and Results

Comparison Studies:

Clinical evaluations were performed to determine the safety and efficiency of Teco Blood Specimen Collection Devices: Vacu lab Plain Tube and Vacu Lab Gel & Clot Activator Tube. The devices were compared to the predicate devices BD Vacutainer ™ Plus SST ™ Tube. The results of the clinical evaluation demonstrated that the Teco Blood Specimen Collection Devices: Vacu lab Plain Tube and Vacu Lab Gel & Clot Activator Tube provide clinically equivalent chemistry analyte results when compared to the BD Vacutainer ™ Plus SST ™ Tube.

Four studies were conducted to evaluate the use of Teco Blood Specimen Collection Devices: Vacu lab Plain Tube and Vacu Lab Gel & Clot Activator Tube in chemistry assays.

Study I was conducted to evaluate the use of the Vacu Lab Plain Tube. The objective of the studies was to demonstrate substantial equivalence to the Becton Dickinson (BD) Vacutainer ™ Plus SST ™ Tube (K023075) when samples from these tubes are used in chemistry assays included total protein, Albumin, Total Bilirubin, Direct Bilirubin, AST, ALT, ALP, r-GT, Cholesterol. A total 66 paired samples were collected from outpatients and samples were tested on Hitachi 717. The Vacu Lab Plain Tube demonstrated equivalent results to the predicate device.

Study II was continuous conducted to evaluate the use of the Vacu Lab Plain Tube. Randomly collect outpatient blood samples 25. Draw the same amount blood from each patient into the Vacu Lab Plain Tube and BD Vacutainer ™ Plus SST ™ Tube and Centrifuge 10 minutes. Test the supernatant. Assays performed on Beckman CX7, Hitachi 912 and Elisa Reader TC98 included potassium, glucose, creatinine, calcium, chloride, creatinine kinase (CK), human chorionic gonadotropin (HCG), magnesium, phosphorous, triglyceride, uric acid, blood urea nitrogen (BUN), sodium, CK-MB, thyroid stimulating hormone (TSH), Free T4, ferritin, prolactin, total protein, albumin, total bilirubin, direct bilirubin, AST, ALT, ALP,r-GT

and Cholesterol. Test conducted within 8 hours after collecting samples. The Vacu Lab Plain Tube demonstrated equivalent results to the predicate device.

Study III was conducted to evaluate the use of Vacu Lab Gel & Clot Activator Tube. The objective of the studies was to demonstrate substantial equivalence to the Becton Dickinson (BD) Vacutainer ™ Plus SST ™ Tube (K023075) when samples from these tubes are used in chemistry assays included total protein, Albumin, Total Bilirubin, Direct Bilirubin, AST, ALT, ALP, r-GT, Cholesterol. A total 70 paired samples were collected from outpatients and samples were tested on Hitachi 717. The Vacu Lab Gel & Clot Activator Tube demonstrated equivalent results to the predicate device.

Study IV was continuous to evaluate the use of Vacu Lab Gel & Clot Activator Tube. Randomly collect outpatient blood samples 25. Draw the same amount blood from each patient into Vacu Lab Gel & Clot Activator Tube and BD Vacutainer ™ Plus SST ™ Tube and Centrifuge 10 minutes. Test the supernatant. Assays performed on Beckman CX7, Hitachi 912 and Elisa Reader TC98 included potassium, glucose, creatinine, calcium, chloride, creatinine kinase (CK), human chorionic gonadotropin (HCG), magnesium, phosphorous, triglyceride, uric acid, blood urea nitrogen (BUN), sodium, CK-MB, thyroid stimulating hormone (TSH), Free T4, ferritin, prolactin, total protein, albumin, total bilirubin, direct bilirubin, AST, ALT, ALP,r-GT and Cholesterol. Test conducted within 8 hours after collecting samples. The Vacu Lab Gel & Clot Activator Tube demonstrated equivalent results to the predicate device.
All comparison studies yield correlation coefficient ≥ 0.95. An acceptable correlation coefficient for all comparison studies is ≥ 0.95

Stability Studies of Specimens

Studies were conducted to compare fresh specimens (8 hours after collecting samples) and 72 hours stored at 2-8 °C. All results showed no significant different from fresh specimens and 72 hours stored at 2-8 °C.

All comparison studies yield correlation coefficient ≥ 0.95. An acceptable correlation coefficient for all comparison studies is ≥ 0.95

Shelf- life Studies

The shelf studies are based on accelerated aging theory, Q_{10} method. Put tubes in 60 centigrade oven for 50 days, to achieve equivalency at least 24 months of real life aging of Vacu Lab Plain Tube and Vacu Lab Gel & Clot Activator Tube at 4-30 centigrade. The calculation as below:

The real time shelf life = Oven aging times (days) X $Q_{10}^{(\text{oven aging temperature-storage temperature})/10} = 50 \times 2^{(60-20)/10} = 50 \times 2^4 = 800$ days. So we claimed that the shelf life is 2 years.
Note: Q_{10}: reaction-rate coeffiecient 2.
Average Storage temperature: 20 centigrade.
Procedure: Put Vacu Lab Plain Tube and Vacu Lab Gel & Clot Activator Tube into 60 centigrade oven for 50 days. After 50 days, we collected 25 outpatient blood specimens. We drew each patient blood into vacu Lab Plain Tubes, Vacu Lab Gel & Clot activator Tubes and BD vacutainer TM Plus SST Tm Tubes to compare studies. All tests were undertaken on Hitach912 and Elisa Reader TC 98. The results of comparison studies did not show any significant difference from the results of BD vacutainer TM Plus SST Tm Tubes.

All comparison studies yield correlation coefficient ≥ 0.95. An acceptable correlation coefficient for all comparison studies is ≥ 0.95

Standard/ Guidance Document Referenced (if applicable)

NCCLS Guideline EP9-A2 —Method Comparison and Bias Estimation Using Patient Samples.
NCCLS H1-A5—Tubes and Additives for Venous Blood Specimen Collection; Approved Standard-5 th, ed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Jian Vaeches
Official FDA Correspondent
TECO Diagnostics
1268 N. Lakeview
Anaheim, CA 92807

JUN 15 2006

Re: k060364
Trade/Device Name: Teco Diagnostics Vacu Lab Plain Tube and Vecu Lab Gel and Clot Activator Tube
Regulation Number: 21 CFR§862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: JKA
Dated: May 30, 2006
Received: May 30, 2006

Dear Mr. Vaeches:

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); 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 060364

Device Name: Teco Diagnostics Vacu Lab Plain Tube and Vecu Lab Gel and Clot Activator Tube

Indications For Use:

1. The Vacu Lab Plain Tube is a sterile, plastic, evacuated blood collection tube with a silica clot activator that provides a means of collecting, transporting, separating, and processing blood in a closed tube. The specimens are used for clinical laboratory assays involving the use of patient serum.
2. The Vacu Lab Gel & Clot Activator Tube is a sterile, plastic, evacuated blood collection tube with a silica clot activator and a barrier gel that provides a means of collecting, transporting, separating, and processing blood in a closed tube. The specimens are used for clinical laboratory assays involving the use of patient serum.

Prescription Use √ AND/OR Over-The-Counter Use _____.
(Part 21 CFR 801 Subpart D) (21 CFR 801 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

(Optional) K060364