



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Teco Diagnostics  
c/o Ms. Jian Vaeches  
R & D Department  
1268 North Lakeview Avenue  
Anaheim, CA 92807

**MAY - 8 2008**

Re: k073370  
Trade Name: TC Matrix Clinical Chemistry Analyzer  
Regulation Number: 21 CFR 862.1345  
Regulation Name: Glucose test system  
Regulatory Class: Class II  
Product Codes: CGA, CKA, CIX, CDQ, JJE, JIX  
Dated: March 12, 2008  
Received: March 24, 2008

Dear Ms. 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).

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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) 276-0490. 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 (240) 276-3150 or at its Internet address at <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

*Jean M. Cooper, M.S., D.V.M.*

Jean M. Cooper, M.S., D.V.M.

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) : K073370

Device Name: TC Matrix Clinical Chemistry Analyzer

### Indications for Use:

The TC Matrix Clinical Chemistry Analyzer is a discrete photometric chemistry analyzer for clinical use. The device is intended to duplicate manual analytical procedures by automatically various steps such as pipetting, heating, and measuring color intensity. This device is intended for use in conjunction with certain materials to measure a variety of analytes of clinical interest in serum, plasma samples.

TECO MULTI Calibrator is intended for the calibration of quantitative assays.

Teco Albumin reagent is intended to measure the albumin concentration in serum and plasma. Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.

Teco ALT reagent is intended to measure the activity of the enzyme alanine amino transferase (ALT) (also known as a serum glutamic pyruvic transaminase or SGPT) in serum and plasma. Alanine amino transferase measurements are used in the diagnosis and treatment of certain liver diseases (e.g., viral hepatitis and cirrhosis) and heart diseases.

Teco Glucose reagent is intended for the quantitative determination of total glucose in human serum or plasma. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Teco BUN reagent is intended to measure urea nitrogen (an end-product of nitrogen metabolism) in serum or plasma. Measurements obtained by this device are used in the diagnosis and treatment of certain renal and metabolic diseases.

Prescription Use

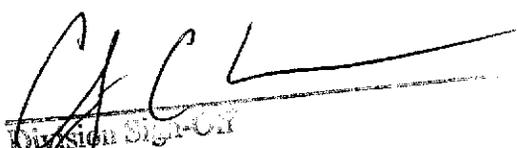
AND/OR

Over-The-Counter Use

(Part 21 CFR 801.109)

(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  
510(k) K073370

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