



TECO Diagnostics  
c/o Andrew Reams  
4925 E. Hunter Avenue  
Anaheim, CA 92807

4 26 2013

Re: k970250  
Trade Name: CLINISTRIP  
Regulation Number: 21 CFR 862.1340  
Regulation Name: Urinary glucose (nonquantitative) test system  
Regulatory Class: Class II  
Product Codes: JIL, LJX, CDM, CEN, JIN, JIR, JJB, JMT, JRE, JIO  
Dated: January 17, 1997  
Received: January 22, 1997

Dear Mr. Reams:

This letter corrects our substantially equivalent letter of April 8, 1997.

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 (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.

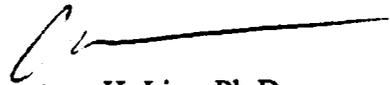
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 Part 801); 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).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Devices and Radiological Health 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) 796-576-. 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 H. Lias, Ph.D  
Director  
Division of Chemistry and Toxicology  
Office of *In Vitro* Diagnostics and  
Radiological Health  
Center for Devices and Radiological Health

Enclosure

Page \_\_\_ of \_\_\_

510(k) Number (if known): \_\_\_\_\_

Device Name: Clinistrip 10 SGL

Indications For Use:

Clinistrip 10 SGL are intend to provide semi-quantitative determination of glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, & leukocytes in urine. Test results may provide information regarding the status of carbohydrate metabolism, kidney & liver function, acid-base balance, & bacteriuria.

(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 K970250

Prescription Use   
(Per 21 CFR 801.109)

OR Over-The-Counter Use

(Optional Format 1-2-96)

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