K972155

JUL 17 1997

STANBIO

510(k) SUMMARY

Submitter's Name
Kirk Johnson
Stanbio Laboratory, Inc.
2930 East Houston Street
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Prepared By Kirk Johnson
May 30, 1997

Product Name
Trade name: Creatine Kinase (CK) Liqui-UV®
Common name: Creatine Kinase (CK)
Classification name: N-Acetyl-L-Cysteine, Creatine Kinase
Class II, 75JFX

Substantial Equivalence of Device
This test is substantially equivalent to :
Product Name: CK/NAC
Manufacturer: Boehringer Mannheim

Description of Device
The device test kit is comprised of two reagents, CK Buffer (R1) and CK Enzyme (R2). A working reagent is prepared by combining five parts CK Buffer (R1) to one part CK Enzyme (R2).

Intended Use of Device
The device is used for the kinetic quantitative determination of Creatine Kinase (CK) in serum.

Comparison of Devices
Both Creatine Kinase (CK) methods measure kinetically the rate of NADPH formation at a rate proportional to the CK activity.

Performance Data
Substantial equivalency was demonstrated by method comparison. Correlation was performed between the two test kits with a correlation coefficient of 0.999 and a regression equation of $y = 1.027x - 0.65$.

In addition, precision, linearity, sensitivity, stability and interference studies were performed on Stanbio Laboratory, Inc., version of Creatine Kinase (CK) Liqui-UV®, Catalog # 2910. Results of these tests were found to be acceptable.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 17 1997

Kirk Johnson
FDA Correspondent
Stanbio Laboratory, Inc.
2930 E. Houston Street
San Antonio, Texas 78202

Re: K972155
Creatine Kinase (CK) Liqui-UV®
Regulatory Class: II
Product Code: CGS
Dated: May 30, 1997
Received: June 5, 1997

Dear Mr. Johnson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 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 Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K972155

Device Name: Creatine Kinase (CK) Liqui-UV

Indications For Use:

Stanbio Laboratory's Creatine Kinase (CK) Liqui-UV is a device intended to measure the activity of the enzyme creatine phosphokinase or its isoenzymes (a group of enzymes with similar biological activity) in serum. Serum creatine kinase (CK) levels have proven valuable in the assessment of cardiac and skeletal muscle diseases, including myocardial infarction and muscular dystrophy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)