K972743

SUMMARY OF SAFETY AND EFFECTIVENESS

CREATININE, PROCEDURE NO. 558

Creatine is synthesized in the kidney, liver and pancreas.[1] It is transported in blood to other organs such as muscle and brain where it is phosphorylated to phosphocreatine. Some free creatine in muscle is converted to creatinine daily and the amount of creatinine produced is proportional to muscle mass. In the absence of renal disease, excretion rate of creatinine in an individual is relatively constant. Therefore, measurement of creatinine clearance is useful in detecting renal disease and estimating the extent of impairment of renal function.[2]

The Sigma Diagnostics procedure is a modification of the Jaffe reaction[3] and is highly adaptable to automation. The rate of color change following the addition of a serum, plasma or urine sample to an alkaline picrate solution is measured between 480 and 520 nm and is proportional to the creatinine concentration in the test specimen.

The safety and effectiveness of the Sigma Diagnostics Creatinine Reagent, Procedure 558 is demonstrated by its substantial equivalency to Boehringer Mannheim Diagnostics Creatinine Reagent, No. 1050702. Both Creatinine test systems are used to measure creatinine concentrations in serum, plasma, or urine and the reaction principles are similar. In comparison studies against BMD using the manual procedure a correlation coefficient of 0.999 and a regression equation $y = 1.11x + 0.05$ was obtained with 128 serum samples. In comparison studies against BMD using the manual procedure a correlation coefficient of 0.998 and a regression equation $y = 1.13x - 0.17$ was obtained with urine samples. With-in run precision and total precision on serum samples indicate acceptable values can be replicated on a day to day basis. Sigma Diagnostics Creatinine reagent has been determined to be linear to 25 mg/dL.

REFERENCES

1. Tietz NW: Textbook of Clinical Chemistry. WB Saunders. Philadelphia, 1986, pp 1271-1281.
2. Bowers LD, Wong ET: Kinetic serum creatinine assays. II.An initial evaluation and review. Clin Chem 26:255, 1980.
3. Jaffe M: Uber den Niederschlag, welchen Picrinsaure in normalen Harn erzeugt und uber eine neue Reaction des Kreatinins. Hoppe Seylers Z Physiol Chem 10:391, 1886.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 22 1997

William R. Gilbert, Ph.D.
Manager, Scientific Affairs
Sigma Diagnostics
545 South Ewing Avenue
St. Louis, MO 63103

Re: K972743
Sigma Diagnostics Creatinine Reagent
Regulatory Class: II
Product Code: CGX
Dated: July 18, 1997
Received: July 23, 1997

Dear Dr. Gilbert:

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 requirements, 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): _____

Device Name: Sigma Diagnostics Creatinine Reagent

Indications For Use:

Sigma Diagnostics Creatinine Reagent is intended to measure creatinine levels in serum, plasma, and urine. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol Benson for Alfred Montgomery

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K972743

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