

K992803

SEP 13 1999

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**INFINITY™ Cholesterol Reagent, Procedure 401**

Sigma Diagnostics INFINITY™ Cholesterol Reagent is intended for the in vitro quantitative, diagnostic determination of cholesterol in human serum and plasma.

Measurement of serum cholesterol levels can serve as an indicator of liver function, biliary function, intestinal absorption, propensity toward coronary artery disease, thyroid function and adrenal disease. Cholesterol levels are important in the diagnosis and classification of hyperlipoproteinaemias. Stress, age, gender, hormonal balance and pregnancy affect normal cholesterol levels.^{1,2}

This reagent is based on the formulation of Allain et al.³ and the modification of Roeschlau⁴ with further improvements to render the reagent stable in solution.

1. Cholesterol esters are enzymatically hydrolyzed by cholesterol esterase (CE) to cholesterol and free fatty acids.
$$\text{Cholesterol Esters} \xrightarrow{\text{CE}} \text{Cholesterol} + \text{Fatty Acids}$$
2. Free cholesterol, including that originally present, is then oxidized by cholesterol oxidase (CO) to cholest-4-en-3-one and hydrogen peroxide.
$$\text{Cholesterol} + \text{O}_2 \xrightarrow{\text{CO}} \text{Cholest-4-en-3-one} + \text{H}_2\text{O}_2$$
3. The hydrogen peroxide combines with hydroxybenzoic acid (HBA) and 4-aminoantipyrine (AAP) in the presence of peroxidase (POD) to form a chromophore (quinoneimine dye) which may be quantitated at 500-550 nm. For bichromatic analyzers the blank wavelength should be set to 600 or 650 nm.
$$2\text{H}_2\text{O}_2 + \text{HBA} + 4\text{AAP} \xrightarrow{\text{POD}} \text{Quinoneimine Dye} + 4\text{H}_2\text{O}$$

The Sigma Diagnostics INFINITY™ Cholesterol Reagent Kit (Procedure No. 401) is substantially equivalent to, and is the same product as the TRACE Scientific Cholesterol Reagent Kit cleared by FDA as K962890.

Correlation studies to Sigma Diagnostics Cholesterol Reagent, Procedure No. 352 (K872295) using plasma samples yielded a regression equation of:

$$\text{INFINITY Cholesterol} = 1.00 (\text{Cholesterol 352}) - 0.3 \quad (N=126)$$

References

1. Searcy R.L. "Diagnostic Biochemistry." McGraw-Hill, New York, NY. 1969.
2. Ellefson R.D. and Caraway W.T. "Fundamentals of Clinical Chemistry." Ed. Tietz N.W. 1976; p 506.
3. Allain C.C., Poon L.S., Chan C.S.G., Richmond W. and Fu P.C. Clin. Chem., 1974; 20:470-475.
4. Roeschlau P., Bernt E. and Gruber W.A. Clin. Chem. Clin. Biochem. 1974; 12:226.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

SEP 13 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

William R. Gilbert, Ph.D.
Manager, Scientific Affairs
SIGMA DIAGNOSTICS®
545 South Ewing Avenue
St. Louis, Missouri 63103

Re: K992803
Trade Name: INFINITY™ CHOLESTEROL Reagent (Procedure No. 401)
Regulatory Class: I reserved
Product Code: CHH
Dated: August 16, 1999
Received: August 19, 1999

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 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). 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.

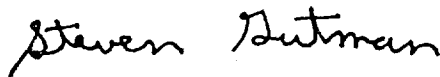
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

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): K992803Device Name: Sigma Diagnostics INFINITY™ Cholesterol Reagent**Indications For Use:**

Sigma Diagnostics INFINITY™ Cholesterol Reagent is intended for the in vitro quantitative, diagnostic determination of cholesterol in human serum or plasma. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.

Jean Cohen
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K992803

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐