JUN 2 0 2005

510(k) Summary

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Contact Person
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Date of Preparation of this Summary:	**May 28, 2005**
Device Trade or Proprietary Name:	Sentinel Cholinesterase Liquid
Device Common/Usual Name or Classification Name:	Cholinesterase
Classification Number/Class:	DIH, DLI/Class I

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K051444

Test Description:

Sentinel Cholinesterase Liquid is an in vitro diagnostic assay for the quantitative determination of cholinesterase in serum and plasma.

Substantial Equivalence:

The modified Sentinel Cholinesterase Liquid assay is substantially equivalent to the cleared Sentinel Cholinesterase Liquid Model Number 17.019A and 17.606 assay on Hitachi 717 (K981800). The modifications consisted of the adaptation of the general purpose Sentinel Cholinesterase Liquid Model Number 17.019A and 17.606 assay to be used on the Abbott AEROSET® and the ARCHITECT® *c*8000® Analyzers. This (these) modifications did not significantly change the safety and effectiveness of the device as demonstrated in the Performance Characteristics Summary.

Intended Use:

The modified Sentinel Cholinesterase Liquid assay is used for the quantitative determination of cholinesterase in serum and plasma.

Performance Characteristics:

Comparative performance studies were conducted using the AEROSET System and the ARCHITECT® *c* 8000® System. For the AEROSET System, the modified Sentinel Cholinesterase Liquid assay method comparison yielded acceptable correlation with the Sentinel Cholinesterase Liquid Model Number 17.019A and 17.606 assay on Hitachi 717. For the ARCHITECT *c*8000 system, the modified Sentinel Cholinesterase Liquid assay method comparison yielded acceptable with the modified Sentinel Cholinesterase Liquid on the AEROSET system. These data demonstrate the performance of the modified Sentinel Cholinesterase Liquid assay is substantially equivalent to the performance of the cleared Sentinel Cholinesterase Liquid Model Number 17.019A and 17.606.

Conclusion:

The modified Sentinel Liquid assay is substantially equivalent to the cleared Sentinel Cholinesterase Liquid Model Number 17.019A and 17.606 (K981800) assay as demonstrated by results obtained in the studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 20 2005

Mr. Davide Spada
Application Specialist
Sentinel CH. S.r.l
Via Principe Eugenio, 5
20155 Milan Italy

Re: k051444
Trade/Device Name: Sentinel Cholinesterase Liquid
Regulation Number: 21 CFR 862.3240
Regulation Name: Cholinesterase test system
Regulatory Class: Class I
Product Code: DIH
Dated: May 28, 2005
Received: June 2, 2005

Dear Mr. Spada:

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).

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) 276-0484. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson

Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K051444

Device Name: Sentinel Cholinesterase Liquid

Indications For Use:

The Sentinel Cholinesterase Liquid assay is used to measure cholinesterase in human specimens. There are two principal type of cholinesterase in human tissues. True cholinesterase is present at nerve endings and in erythrocytes but is not present in plasma. Pseudo cholinesterase is present in plasma and liver but is note present in erythrocytes. Measurements obtained by this device are used in the diagnosis and treatment of cholinesterase inhibition and disorders. For In Vitro diagnostics use only. CFR 862.3240

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(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) 051444