K973414

510(k) PREMARKET NOTIFICATION
ACE® Phenytoin Reagent

NOV - 4 1997

SUMMARY OF SAFETY AND EFFECTIVENESS

In lieu of a 510(k) statement under 513(i) of the Act, this Summary of Safety and Effectiveness is provided as a 510(k) summary for disclosure to any other persons/companies without specific written authorization from Schiapparelli Biosystems, Inc.

Submitter
Schiapparelli Biosystems, Inc.
368 Passaic Avenue
Fairfield, NJ 07004
Phone: (973) 882-8630

Contact Person
Steven Dalessio
Manager, Quality Assurance/Regulatory Affairs
Phone: (973) 882-8630

Device Names

Proprietary Name:	ACE® Phenytoin Reagent
Common Name:	Enzyme immunoassay for phenytoin (diphenylhydantoin or Dilantin®)
Classification Name:	Phenytoin test
Predicate Device:	Diagnostic Reagents, Inc. (DRI) - Phenytoin Reagent [510(k) Number K945725]

Device Description

The ACE® Phenytoin Reagent contains two reagents, an Antibody/Substrate reagent and an Enzyme Conjugate reagent. The assay uses specific antibodies to phenytoin and is based on the competition of an enzyme glucose-6-phosphate dehydrogenase (G6PDH) labeled drug and the free drug from the sample, for a fixed amount of specific antibody binding sites. In the absence of free drug from the sample, the drug-labeled G6PDH is bound by the specific antibody and the enzyme activity is inhibited. This phenomenon creates a relationship between drug concentration in the sample and the enzyme activity. The enzyme G6PDH activity is determined bichromatically on the ACE® at 340/505 nm by measuring its ability to convert NAD^+ to NADH.

Intended Use of the Device
ACE® Phenytoin Reagent is intended for use in the quantitative determination of phenytoin in human serum.

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COMPARATIVE FEATURES OF PREDICATE AND PROPOSED DEVICES

PARAMETER	PREDICATE DEVICE	PROPOSED DEVICE
Trade Name	DRI Phenytoin Enzyme Immunoassay	ACE® Phenytoin Reagent
Reference No.	K945725/S1	TBD
Analyte	Phenytoin	Phenytoin
Intended Use	Quantitative determination of phenytoin	Quatitative determination of phenytoin
Methodology	Enzyme immunoassay	Enzyme immunoassay
Reagents **Reagent 1** **Volume** **Reagent 2** **Volume**	 Liquid; Antibody/Substrate 210 µL Liquid; Enzyme conjugate 70 µL	 Liquid; Antibody/Substrate 210 µL Liquid; Enzyme conjugate 70 µL
Specimen **Type** **Volume**	 Serum and plasma 5 µL	 Serum 5 µL
Assay System **Reagent 1 + Sample** **Reagent 2** **Temperature**	 Incubate 300 sec Read 60 and 120 sec 37 °C	 Incubate 240 sec Read 63 and 203 sec 37 °C
Detection Method **Type** **Wavelength, nm**	 Spectrophotometric Bichromatic: 340/505	 Spectrophotometric Bichromatic: 340/505

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PERFORMANCE ASSESSMENT

Non-clinical test results submitted in the premarket notification include within-run and between-run precision and method correlation. Following is a data summary.

PARAMETER	PREDICATE DEVICE	PROPOSED DEVICE
Performance Summary		
Assay Range	0.3 µg/mL to 40 µg/mL	0.6 µg/mL to 40 µg/mL
Precision		
Within Run	<5.5 %CV	<7.9 %CV
Between Run	<5.9 %CV	<11.7 %CV
Correlation vs	**Commercial phenytoin assay**	**Hitachi 717**
Slope	1.01	1.119
Intercept	0.17	-0.51
r	0.97	0.993
N	90	49

Based on these data, the Schiapparelli Biosystems ACE® Phenytoin Reagent is substantially equivalent to the predicate device (Diagnostic Reagents, Inc. Phenytoin Enzyme Immunoassay). On this basis, the reagent is determined to be safe and effective for its intended use. Performance details are included in the reagent product labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV - 4 1997

Steven Dalessio
Manager, Quality Assurance/Regulatory Affairs
Schiapparelli Biosystems, Inc.
368 Passaic Avenue
Fairfield, New Jersey 07004

Re: K973414
ACE® Phynetoin Reagent, AED Calibrators
Regulatory Class: II
Product Code: DIP
Dated: September 8, 1997
Received: September 9, 1997

Dear Mr. Dalessio:

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: ACE® Phenytoin Reagent

Indications For Use:

ACE® Phenytoin Reagent is intended for the quantitative determination of phenytoin in serum using the ACE® clinical chemistry analyzer.

Phenytoin is one of the most widely prescribed anti-convulsant drugs for the treatment of epilepsy, particulary grand mal epilepsy (major motor), corticol focal seizures and temporal lobe epilepsy.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K973414

(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)