

**510(k) PREMARKET NOTIFICATION  
ACE® Phenobarbital Reagent**

NOV - 6 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® Phenobarbital Reagent  
**Common Name:** Enzyme immunoassay for phenobarbital  
**Classification Name:** Phenobarbital test

**Predicate Device:** Diagnostic Reagents, Inc. (DRI) - Phenobarbital Reagent [510(k) Number K946210]

**Device Description**

The ACE® Phenobarbital Reagent contains two reagents, an Antibody/Substrate reagent and an Enzyme Conjugate reagent. The assay uses specific antibodies to phenobarbital 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<sup>+</sup> to NADH.

**Intended Use of the Device**

ACE® Phenobarbital Reagent is intended for use in the quantitative determination of phenobarbital in human serum.

**510(k) PREMARKET NOTIFICATION  
ACE® Phenobarbital Reagent**

**SUMMARY OF SAFETY AND EFFECTIVENESS**

**COMPARATIVE FEATURES OF PREDICATE AND PROPOSED DEVICES**

<b>PARAMETER</b>	<b>PREDICATE DEVICE</b>	<b>PROPOSED DEVICE</b>
<b>Trade Name</b>	DRI Phenobarbital Enzyme Immunoassay	ACE® Phenobarbital Reagent
<b>Reference No.</b>	K946210	TBD
<b>Analyte</b>	Phenobarbital	Phenobarbital
<b>Intended Use</b>	Quantitative determination of phenobarbital	Quantitative determination of phenobarbital
<b>Methodology</b>	Enzyme immunoassay	Enzyme immunoassay
<b>Reagents</b>		
<b>Reagent 1 Volume</b>	Liquid; Antibody/Substrate 210 µL	Liquid; Antibody/Substrate 210 µL
<b>Reagent 2 Volume</b>	Liquid; Enzyme conjugate 70 µL	Liquid; Enzyme conjugate 70 µL
<b>Specimen</b>		
<b>Type</b>	Serum and plasma	Serum
<b>Volume</b>	5 µL	5 µL
<b>Assay System</b>		
<b>Reagent 1 + Sample</b>	Incubate 300 sec	Incubate 240 sec
<b>Reagent 2</b>	Read 60 and 120 sec	Read 63 and 203 sec
<b>Temperature</b>	37 °C	37 °C
<b>Detection Method</b>		
<b>Type</b>	Spectrophotometric	Spectrophotometric
<b>Wavelength, nm</b>	Bichromatic: 340/505	Bichromatic: 340/505

**510(k) PREMARKET NOTIFICATION  
ACE® Phenobarbital Reagent**

**SUMMARY OF SAFETY AND EFFECTIVENESS**

**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.

<b>PARAMETER</b>	<b>PREDICATE DEVICE</b>	<b>PROPOSED DEVICE</b>
<b>Performance Summary</b>		
<b>Assay Range</b>	0.5 µg/mL to 80 µg/mL	1.3 µg/mL to 80 µg/mL
<b>Precision</b>		
<b>    Within Run</b>	<5.4 %CV	<6.7 %CV
<b>    Between Run</b>	<6.8 %CV	<10.8 %CV
<b>Correlation vs</b>	<b>Commercial Phenobarbital assay</b>	<b>Hitachi 717</b>
<b>    Slope</b>	1.00	1.067
<b>    Intercept</b>	0.9	-1.26
<b>    r</b>	0.992	0.972
<b>    N</b>	80	45

Based on these data, the Schiapparelli Biosystems ACE® Phenobarbital Reagent is substantially equivalent to the predicate device (Diagnostic Reagents, Inc. Phenobarbital 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.



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

NOV - 6 1997

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

Re: K973536  
ACE® Phenobarbital Reagent  
Regulatory Class: II  
Product Code: DLJ  
Dated: October 24, 1997  
Received: October 27, 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 (Pre-market 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.

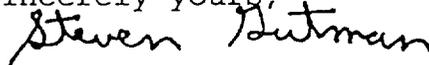
Page 2

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 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® Phenobarbital Reagent

Indications For Use:

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

Since its discovery by Hauptmann in 1912, phenobarbital has been widely prescribed for the treatment of epilepsy, particularly for controlling focal motor or sensory and grand mal seizures. In combination with other clinical information, monitoring serum phenobarbital levels will provide physicians with an essential tool to aid in adjusting dosage and achieving optimal therapeutic effect, while avoiding both subtherapeutic and harmful toxic drug levels.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia A. Bernhart  
(Division of Medical Devices) (for ADOM)  
510(k) Number K973536

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)