K970510

OXIS International, Inc.

MAY 12 1997

510(k) SUMMARY
INNOFLUOR™ TOPIRAMATE REAGENT SET

Trade Name: INNOFLUOR™ Topiramate Assay System, which consists of three products that are packaged and sold separately: the INNOFLUOR™ Topiramate Reagent Set, the INNOFLUOR™ Topiramate Calibrator Set and the INNOFLUOR™ Topiramate Control Set.

Common or Usual Name: Topiramate Fluorescence Polarization Immunoassay

Classification Name: Fluorescence Polarization Immunoassay, Topiramate

The INNOFLUOR™ Topiramate Assay System is a fluorescence polarization immunoassay intended for the quantitative determination of total topiramate in serum or heparinized plasma. Topiramate serum or heparinized plasma concentrations are measured to aid in achieving appropriate therapy. The assay system is for use on the Abbott TDx® or the TDxFLx® analyzer.

Substantial equivalence has been demonstrated between the INNOFLUOR™ Topiramate Assay System, the INNOFLUOR™ Phenobarbital Assay System (INNOFLUOR™ Phenobarbital Reagent Set and INNOFLUOR™ Phenobarbital Calibrator Set), the Abbott Phenobarbital II Assay and Topiramate Gas Chromatography.

The technological characteristics, performance and intended use of the INNOFLUOR™ Topiramate Assay System are substantially equivalent to the INNOFLUOR™ Phenobarbital Assay System and the Abbott Phenobarbital II Assay with the exception of the specific anticonvulsant tested for by each method.

Topiramate concentrations measured by the INNOFLUOR™ Topiramate Assay System (INNOFLUOR™), on the Abbott TDx® analyzer, were compared with those measured by Topiramate Gas Chromatography (GC) on 117 patient samples from patients receiving topiramate therapy. Comparison of the patient sample results by linear regression analysis resulted in the regression equation: (INNOFLUOR™) = 0.985 x (GC) - 0.147, with a correlation coefficient of 0.9934, demonstrating equivalency of results.

Contact Person: Lynda M. Taylor
Vice President Quality Assurance and Regulatory Affairs

Date Prepared: 05/09/97

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Corporate Headquarters
6040 N. Cutter Circle, Suite 317, Portland, OR 97217-3935
Voice: 503-283-3911 • 800 547-3686 • Facsimile: 503-283-4058

European Operations
Z.A. des Petits Carreaux, 2, av. des Coquelicots, 94385 BONNEUIL-SUR-MARNE CEDEX FRANCE
Voice: 33 1 49 80 45 65 • Facsimile: 33 1 49 80 01 66

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Letter date: November 2, 2012

OXIS International
c/o Lynda M. Taylor
6040 N. Cutter Circle, Suite 317
Portland, OR 97217-3935

Re: k970510
Trade/Device Name: INNOFLUOR™ Topiramate Reagent Set
Regulation Number: 21 CFR§862.3350
Regulation Name: Diphenylhydantoin Test System
Regulatory Class: II
Product Code: MSL, DIP
Dated: February 7, 1997
Received: February 11, 1997

Dear Ms. Taylor:

This letter corrects our substantially equivalent letter of May 12, 1997.

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 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 (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 additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson

Digitally signed by Carol C. Benson
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Carol C. Benson, 0.9.2342.19200300.100.1.1=1300086490
Date: 2012.11.02 15:28:26 -04'00'

Courtney H. Lias, Ph.D
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics and
Radiological Health
Center for Devices and Radiological Health

510(k) Number (If known): K970510

Device Name: INNOFLUOR Topiramate Reagent Set

Indications For Use:

The INNOFLUOR™ Topiramate Reagent Set, the INNOFLUOR™ Topiramate Calibrator Set and the INNOFLUOR™ Topiramate Control Set are packaged and sold separately, but are referred to collectively, in all associated product labeling, as the INNOFLUOR™ Topiramate Assay System.

The INNOFLUOR™ Topiramate Assay System is an *in vitro* diagnostic device intended for the quantitative determination of total topiramate in serum or heparinized plasma by fluorescence polarization immunoassay. Topiramate serum or heparinized plasma concentrations are measured to aid in achieving appropriate therapy. The assay system is for use on the Abbott TDx® or the TDxFLx® (TDx®/TDxFLx®) analyzer.

The INNOFLUOR™ Topiramate Reagent Set is intended for the quantitative determination of total topiramate in serum or heparinized plasma. The reagent set is intended for use in the INNOFLUOR™ Topiramate Assay System. The INNOFLUOR™ Topiramate Calibrator Set is intended for use in the calibration of the INNOFLUOR™ Topiramate Assay System. The INNOFLUOR™ Topiramate Reagent Set and Calibrator Set are used together to generate the calibration curve on the TDx®/TDxFLx® analyzer. The calibration curve must be established prior to assaying unknown samples. Prior to performing the calibration procedure, the correct analyzer operating parameters must be set by following the instructions provided in the Product Insert Supplement, which is included with every INNOFLUOR™ Topiramate Reagent Set. The INNOFLUOR™ Topiramate Control Set is intended for use in the quality control of the INNOFLUOR™ Topiramate Assay System. The concentrations of the three levels of the controls have been selected to best monitor the quality and stability of the calibration curve. The control results must be within established acceptable ranges before patient samples are assayed.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K970510

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

(Optional Format 1-2-96)

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