K 972331

AUG - 1 1997

510(k) SUMMARY
INNOFLUOR® GENTAMICIN REAGENT SET

Trade Name: INNOFLUOR® Gentamicin Assay System, which consists of two products that are packaged and sold separately: the INNOFLUOR® Gentamicin Reagent Set and the INNOFLUOR® Gentamicin Calibrator Set.

Common or Usual Name: Gentamicin Fluorescence Polarization Immunoassay

Classification Name: Fluorescence Polarization Immunoassay, Gentamicin

The INNOFLUOR® Gentamicin Assay System is a fluorescence polarization immunoassay intended for the quantitative determination of total gentamicin in serum for therapeutic drug monitoring. The assay system is for use on the Abbott TDx® or the TDxFLx® analyzer.

Substantial equivalence has been demonstrated between the INNOFLUOR® Gentamicin Assay System, Modified, the INNOFLUOR® Gentamicin Assay System, Existing and the Abbott Gentamicin Assay.

The technological characteristics, performance and intended use of the INNOFLUOR® Gentamicin Assay System, Modified are substantially equivalent to the INNOFLUOR® Gentamicin Assay System, Existing and the Abbott Gentamicin Assay.

Gentamicin concentrations measured by the INNOFLUOR® Gentamicin Assay System, Modified, (INNOFLUOR®, Modified), and the INNOFLUOR® Gentamicin Assay System, Existing, (INNOFLUOR®, Existing), were compared with those measured by the Abbott Gentamicin Assay (Abbott), using the Abbott TDx® analyzer, on 69 patient samples from patients receiving gentamicin therapy. Comparison of the patient sample results by linear regression analysis resulted in the regression equations: (INNOFLUOR®, Modified) = 0.985 x (Abbott) - 0.107, with a correlation coefficient of 0.9928 and (INNOFLUOR®, Modified) = 1.037 x (INNOFLUOR®, Existing) - 0.045, with a correlation coefficient of 0.9947, demonstrating equivalency of results.

Contact Person: Lynda M. Taylor
Vice President, Technical Operations and Regulatory Affairs

Date Prepared: April 22, 1997

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG - 1 1997

Lynda M. Taylor
Vice President, Technical Operations
OXIS International, Inc.
6040 N. Cutter Circle, Suite 317
Portland, Oregon 97217-3935

Re: K972331
INNOFLUOR™ Gentamicin Reagent Set
Regulatory Class: II
Product Code: LGQ
Dated: June 20, 1997
Received: June 23, 1997

Dear Ms. Taylor:

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 requirement, 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

STATEMENT OF INDICATIONS FOR USE

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

The INNOFLUOR® Gentamicin Assay System is an *in vitro* diagnostic device intended for the quantitative determination of total Gentamicin in serum for therapeutic drug monitoring by fluorescence polarization immunoassay. The assay system is for use on the Abbott TDx® or the TDxFLx® analyzer.

The INNOFLUOR® Gentamicin Reagent Set is intended for the quantitative determination of total gentamicin in serum for therapeutic drug monitoring. The reagent set is intended for use in the INNOFLUOR® Gentamicin Assay System.

The INNOFLUOR® Gentamicin Calibrator Set is intended for use in the calibration of the INNOFLUOR® Gentamicin Assay System.

The INNOFLUOR® Gentamicin 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® Gentamicin Reagent Set.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K973331

TDx® and TDxFLx® are registered trademarks of Abbott Laboratories, Inc., Abbott Park, IL 60064