OCT 2 8 2002

510(k) Summary

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

The assigned 510(k) number is: K021541.

Date: 3/28/01

Submitted by: PerkinElmer Life Sciences
3985 Eastern Rd.
Norton, OH 44203

Telephone: 330-825-4525
Fax: 330-825-8520

Contact person: Hank Juske, Director, Regulatory Affairs

Trade name: NeoGram PKU Tandem Mass Spectrometry Kit (MS-7960)
Common name: Phenylalanine screening test kit
Classification name: Phenylalanine test system

Legally marketed predicate device: Isolab Phenylalanine Test Kit

Device description: The assay involves the extraction of dried blood spots with a solution containing stable, isotopically labeled internal standards. The response of each amino acid relative to the isotopically labeled standards in the kit is proportional to their actual concentration. The analysis of the material is performed on a tandem mass spectrometer. Control material contained in the kit allows for verification of performance for the test run.

Intended use: The NeoGram PKU Tandem Mass Spectrometry Kit is intended for screening for Phenylketonuria (PKU). It involves the quantitative determination of phenylalanine, tyrosine and the phenylalanine to tyrosine ratio (Phe/Tyr) in blood specimens dried on filter paper. This will aid in identifying newborns with PKU. It is intended for use by trained, qualified laboratory personnel.

Similarities/ Differences with the predicate device:

Similarities:
-Intended use is the same. Both kits are for screening of newborns.
-Both kits are intended to screen for the defect PKU.
-Both measure the analyte Phenylalanine
-Both use dried blood spots on filter paper for sample collection
-Both use standards and controls dried onto filter paper
-Both assays are quantitative
-Sample size (3mm punched spot) is the same
-Both employ a 96 well microtiter plate

Differences: -Fluorometric based chemistry vs. spectrometric assay
-Linearity of approximately 21mg/dl fluorometric vs. 35 mg/dl TMS
-Measurement by calibration curve versus internal standard comparison
-Zinc sulfate/ethanol extraction solution vs. methanol / water solution

Mean value/ standard deviation of 3679 samples run by:

Fluorometric method: X= 1.1 mg/dl S.D.= 0.3

Tandem Mass Method: X= 1.1 mg/dl S.D.= 0.2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 2 8 2002

Ms. Carroll Martin
Regulatory Affairs Manager
PerkinElmer Life Sciences, Inc.
3985 Eastern Road
Norton, Ohio 44203

Re: k021541
Trade/Device Name: NeoGram PKU Tandem Mass Spectrometry Kit
Regulation Number: 21 CFR 862.1555
Regulation Name: Phenylalanine test system
Regulatory Class: Class II
Product Code: JNB; CDR; JJE
Dated: August 21, 2002
Received: August 22, 2002

Dear Ms. Martin:

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 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); 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.

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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/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

PerkinElmer™
life sciences.

PerkinElmer Life Sciences
3985 Eastern Rd.
Norton, OH 44321
Phone: 330-825-4525
Fax330-825-8520
http://www.perkinelmer.com

INDICATIONS FOR USE STATEMENT

510(K) Number K021541

Device name: NeoGram PKU Tandem Mass Spectrometry Kit

Indications for use: The kit is intended for screening for phenylketonuria (PKU). It involves the quantitative determination of phenylalanine, tyrosine and the phenylalanine to tyrosine ratio (Phe/Tyr) in blood specimens dried on filter paper. This will aid in identifying newborns with PKU. It is intended for use by trained, qualified laboratory personnel.

Stan Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021541

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (per 21 CFR 801.109) or Over-the-Counter Use

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021541