DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Cindy Lloyd, RAC
Manager, Regulatory Affairs
PerkinElmer Life and Analytical Sciences
3985 Eastern Road
Norton, OH 44203

AUG 24 2004

Re: k031878
Evaluation of Automatic Class III Designation
NeoGram Amino Acids and Acylcarnitines Tandem Mass Spectrometry Kit, Model MS-8970
Regulation Number: 21 CFR 862.1055
Classification: Class II
Product Code: NQL

Dear Ms. Lloyd:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your petition for classification of the NeoGram Amino Acids and Acylcarnitines Tandem Mass Spectrometry Kit, Model MS-8970 that is intended for use in the measurement and evaluation of amino acid, free carnitine and acylcarnitine concentrations from newborn heel prick blood samples dried on filter paper to provide analyte concentration profiles that may aid in the screening of newborns for one or more inborn errors of metabolism. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the NeoGram Amino Acids and Acylcarnitines Tandem Mass Spectrometry Kit, Model MS-8970, and substantially equivalent devices of this generic type into class II under the generic name, Newborn Screening Test System for Amino Acids, Free Carnitine and Acylcarnitines by Tandem Mass Spectrometry. This order also identifies the special controls applicable to this device.

FDA identifies this generic type of device as:

21 CFR 862.1055 – Newborn Screening Test System for Amino Acids, Free Carnitine and Acylcarnitines by Tandem Mass Spectrometry

A newborn screening test system for amino acids, free carnitine and acylcarnitines by tandem mass spectrometry is a device that consists of stable isotope internal standards, control materials, extraction solutions, flow solvents, instrumentation, software packages, and other reagents and materials. The quantitative analysis of amino acids, free carnitines and acylcarnitines and their relationship with each other is intended to provide analyte concentration profiles that may aid in screening newborns for one or more inborn errors of amino acid, free carnitine, and acylcarnitine metabolism.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) for a device may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request classify the device. This classification shall be the initial classification of the device type. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register classifying the device type.

On July 02, 2004, FDA filed your petition requesting classification of the NeoGram Amino Acids and Acylcarnitines Tandem Mass Spectrometry Kit, Model MS-8970 into class II. The petition was submitted under section 513(f)(2) of the act. In accordance with section 513(f)(1) of the act, FDA issued an order on June 09, 2004, automatically classifying the NeoGram Amino Acids and Acylcarnitines Tandem Mass Spectrometry Kit Model MS-8970 in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, which was subsequently reclassified into class I or class II. In order to classify the NeoGram Amino Acids and Acylcarnitines Tandem Mass Spectrometry Kit, Model MS-8970 into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the petition, FDA has determined that the NeoGram Amino Acids and Acylcarnitines Tandem Mass Spectrometry Kit, Model MS-8970, intended for use in the measurement and evaluation of amino acid, free carnitine and acylcarnitine concentrations from newborn heel prick blood samples dried on filter paper, to provide analyte concentration profiles that may aid in the screening of newborns for one or more inborn errors of metabolism can be classified in class II with the establishment of special controls. FDA believes that class II special controls provide reasonable assurance of the safety and effectiveness of the device.

FDA has identified no direct risks to health related to use of newborn screening test systems for amino acids, free carnitine and acylcarnitines by tandem mass spectrometry. However, failure of the test to perform as indicated or error in interpretation of results may lead to improper medical management of patients with inborn errors of metabolism. A falsely low (e.g. false negative / false normal) measurement could contribute to failure to detect a possible inborn error of metabolism, which could lead to functional impairment or death. A falsely high (e.g. false positive / false abnormal) measurement could contribute to unnecessary additional patient testing and added concern and apprehension of parents and physicians. The measures FDA recommends to mitigate these risks are described in the guidance document, "Class II Special Controls Guidance Document: Newborn Screening Test Systems for Amino Acids, Free Carnitine and Acylcarnitines by Tandem Mass Spectrometry", which includes recommendations for performance validation and labeling.

In addition to the general controls of the act, Newborn Screening Test Systems for Amino Acids, Free Carnitine and Acylcarnitines by Tandem Mass Spectrometry are subject to the following special controls: "Class II Special Controls Guidance Document: Newborn Screening Test Systems for Amino Acids, Free Carnitine and Acylcarnitines by Tandem Mass Spectrometry". Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device and, therefore, the device is not exempt from the premarket notification requirements. Thus, persons who intend to market this device must submit to FDA a premarket notification submission containing information on the newborn screening test system for amino acids, free carnitine and acylcarnitines by tandem mass spectrometry they intend to market prior to marketing the device.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market this device, subject to the general control provisions of the act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Carol C. Benson at (301) 594-1243.

Sincerely yours,

Steven Gutman, M.D.

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