



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

FEB 15 2000

Mr. Hank Juske  
Director, Regulatory Affairs  
PerkinElmer, Inc.  
3985 Eastern Road  
Norton, Ohio 44203-6215

Re: K992284  
Evaluation of Automatic Class III Designation  
Wallac Neonatal Biotinidase Test Kit

Dear Mr. Juske,

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 Wallac Neonatal Biotinidase Test Kit that is intended for use in the semi-quantitative in vitro determination of biotinidase activity in blood specimens collected onto filter paper to screen newborns for biotinidase deficiency, an inborn error 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 Wallac Neonatal Biotinidase Test Kit, and substantially equivalent devices of this generic type into class II under the generic name, biotinidase test system. This order also identifies the special control applicable to this device.

FDA identifies this generic type of device as a clinical chemistry in vitro diagnostic device under 21 CFR 862.1118, a biotinidase test system, which is intended to measure the activity of the enzyme biotinidase in blood. Measurements of biotinidase are used in the treatment and diagnosis of biotinidase deficiency, an inborn error of metabolism in infants, characterized by the inability to utilize dietary protein bound vitamin or to recycle endogenous biotin and may result in irreversible neurological impairment.

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 postamendment 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. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device.

On December 20, 1999, FDA filed your petition requesting classification of the Wallac Neonatal Biotinidase Test Kit 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 November 19, 1999, automatically classifying the Wallac Neonatal Biotinidase Test Kit 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, or which was subsequently reclassified into class I or class II. In order to classify the Wallac Neonatal Biotinidase Test Kit 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 Wallac Neonatal Biotinidase Test Kit intended for use in the semi-quantitative in vitro determination of biotinidase activity in blood specimens collected onto filter paper to screen newborns for biotinidase deficiency, an inborn error of metabolism, can be classified in class II with the establishment of a special control. FDA believes that the class II special control provides reasonable assurance of the safety and effectiveness of the device.

FDA has identified the following potential risks associated with this type of device: 1) misdiagnosis due to the performance of the device and 2) misuse of the device and misinterpretation of the test results by an untrained individual.

In addition to the general controls of the act, the Wallac Neonatal Biotinidase Test Kit is subject to the following special controls: 1) the sale, distribution and use of this device are restricted to prescription use in accordance with 21 CFR 801.109. 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

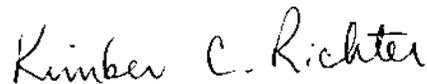
exempt from the premarket notification requirements. Thus, persons who intend to market this device must submit to FDA a premarket notification submission containing information on the biotinidase test system they intend to market and receive clearance prior to marketing the device.

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, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857 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 control identified in this order.

If you have any questions concerning this classification order, please contact Jean Cooper, D.V.M. at 301-594-1243.

Sincerely,

Handwritten signature of Kimber C. Richter in cursive script.

Kimber Richter, M.D.  
Deputy Director for Clinical  
and Review Policy  
Office of Device Evaluation  
Center for Devices and Radiological Health