DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 3 2004

Robert Lipshutz
Sr. Vice President
Affymetrix, Inc.
3380 Central Expressway
Santa Clara, CA 95051

Re: k042279
Evaluation of Automatic Class III Designation
Affymetrix GeneChip® Microarray Instrumentation System
Regulation Number: 21 CFR 862.2570
Classification: Class II
Product Code: NSU

Dear Dr. Lipshutz:

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 Affymetrix GeneChip®Microarray Instrumentation System consisting of GeneChip® 3000Dx scanner with autoloader, FS45Dx fluidics station and GCOSDx software is intended to measure fluorescence signals of labeled DNA target hybridized to GeneChip® arrays. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the Affymetrix GeneChip® Microarray Instrumentation System, and substantially equivalent devices of this generic type into class II under the generic name, Instrumentation for Clinical Multiplex Test Systems. This order also identifies the special controls applicable to this device.

FDA identifies this generic type of device as:

21 CFR §862.2570 – Instrumentation for Clinical Multiplex Test Systems. Instrumentation for clinical multiplex test systems is a device intended to measure and sort multiple signals generated by an assay from a clinical sample. This instrumentation is used with a specific assay to measure multiple similar analytes that establish a single indicator to aid in diagnosis. Such instrumentation may be compatible with more than one specific assay. The device includes a signal reader unit, and may also integrate reagent handling, hybridization, washing, dedicated instrument control, and other hardware components, as well as raw data storage mechanisms, data acquisition software, and software to process detected signals.

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 type. 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 type.

On November 3, 2004, FDA filed your petition requesting classification of the Affymetrix GeneChip® Microarray Instrumentation System 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 October 29, 2004, automatically classifying the Affymetrix GeneChip® Microarray Instrumentation System 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 Affymetrix GeneChip® Microarray Instrumentation System 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 Affymetrix GeneChip® Microarray Instrumentation System 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 instrumentation for clinical multiplex test systems. However, inaccurate results could lead to inaccurate diagnoses or inappropriate patient management. In addition, failure of the instrumentation to generate any results at all can deny or delay beneficial, appropriate therapies. The measures FDA recommends to mitigate these risks are described in the guidance document, "Class II Special Controls Guidance Document: Instrumentation for Clinical Multiplex Test Systems", which includes recommendations for performance validation and labeling.

In addition to the general controls of the act, the Affymetrix GeneChip® Microarray Instrumentation System is subject to the following special controls: "Class II Special Controls Guidance Document: Instrumentation for Clinical Multiplex Test Systems." 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 Instrumentation for Clinical Multiplex Test Systems 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 begin marketing your device subject to the general control provisions of the act, and the special controls identified in this order. If you have questions concerning this classification order, please contact Courtney Harper at (240) 276-0443.

Sincerely yours,

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
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