

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE**

A. 510(k) Number:

k080995

B. Purpose for Submission:

New indication for the Affymetrix GeneChip Microarray Instrumentation System to measure fluorescence signals of labeled RNA

C. Manufacturer and Instrument Name:

Affymetrix, Inc.

Modification to Affymetrix Genechip Microarray Instrumentation System

D. Type of Test or Tests performed:

Hybridization, washing, scanning, and data analysis of GeneChip microarrays

E. System Descriptions:

1. Device Description:

The Affymetrix GeneChip Microarray Instrumentation System is designed to work with microarrays based on Affymetrix GeneChip ® technology.

FS450Dx Fluidics Station

The FS450Dx (Fluidics Station) is an instrument consisting of four modules installed in a single Station or housing. Each module holds a single GeneChip microarray and performs the functions required for hybridization, washing, and staining of that array. Up to 8 stations communicate to a workstation. Each module contains controls the addition of target and staining fluids to the array cartridge and subsequent washing of the array. The module contains a pump, valve, thermo-electric system, and LCD that are controlled by scripts selected by the system operator and automatically downloaded to each module, then stored in the module's electronic memory.

GCS3000Dx Scanner

The GCS3000Dx Scanner is a wide-field, epifluorescent, confocal, scanning laser microscope which scans the chip after the staining process performed by the Fluidics Station. Array cartridges are loaded into the scanner by an automatic handler (the Autoloader) prior to scanning, and returned to the handler after scanning is complete.

GCOSDx Software

The GeneChip® Operating Software (GCOSDx) provides the interface between the user and instrument systems. It is the software that provides instrument control and the application for processing arrays and data collection. Upon completion of scanning of the array, data is passed through GCOSDx to the assay specific software component that contains the algorithms and reporting functions to produce a clinical result.

2. Principles of Operation:

a. Device Features Controlled by Software

- i. The GeneChip® Operating Software (GCOSDx) provides the interface between the user and the instruments. GCOSDx controls the FS450Dx, GCS3000Dx and the AutoLoaderDx. GCOSDx may also be used to monitor the operations being performed by each instrument.
- ii. GCOSDx controls the fluidics station using fluidics scripts specific to the assay being performed. Fluidics scripts are written to a directory specified during GCOSDx installation.
- iii. GCOSDx aids and controls scanner movement and image capture including grid alignment. GCOSDx displays a picture of the scan image in an image window on the computer workstation. The software represents the fluorescence intensity values from each pixel on the array in a grayscale or pseudocolor mode. This image is saved as a “.dat” file format.
- iv. GCOSDx then uses an alignment algorithm to superimpose a grid on the image to delineate probe cells. The alignment algorithm uses a checkerboard image of control probes, located at the corners of the probe array to superimpose the grid on the scanned image. GCOSDx generates cell intensity data from the image data. The cell analysis algorithm analyzes the image data and computes a single intensity value for each probe cell on the array. This data is saved as a “.cel” file. It is the “.cel” file that is handed to the assay specific software for final data analysis and result reporting.

b. Operational Environment (Off-The-Shelf Software)

GCOSDx is programmed in C++. GCOSDx functions on MicroSoft® Windows® 2000 SP3 or SP4 Operating System. The work stations also include Internet Explorer 6.0, Office XP and MDAC 2.7 SP1. The operating system will be moved to MicroSoft® XP in the near future. Prior to this shift, the appropriate validations will be performed. Dell workstations included with the system must have 750 MHz to 3.0 GHz Processor speed as well as 256 Mbyte to 1 Gbyte Memory and a 10 Gbyte to 80 Gbyte Hard Drive.

3. Modes of Operation:

batch - the scanner automatically loads and unloads chips from the autoloader

4. Specimen Identification:

The operator enters patients ID information in tied to a barcode on the chip.
The barcode is scanned at the level of the fluidics station and the scanner.

5. Specimen Sampling and Handling:

Specimens are processed according to assay instructions. Reagents specific to each assay and fluidics protocol are manually loaded onto the fluidics station.

6. Calibration:

Installation and calibration are performed by the sponsor. No user calibration required.

7. Quality Control:

Quality control is addressed for each specific assay to be run on the system (separately cleared)

8. Software:

FDA has reviewed the applicant's Hazard Analysis and software
Documentation: Yes X or No _____

F. Regulatory Information:

1. Regulation Section:

21CFR § -862.2570 Instrumentation for clinical multiplex test systems.

2. Classification:

Class II

3. Product Code:

NSU

4. Panel:

Clinical Chemistry (75)

G. Intended Use:

1. Indication(s) for Use:

The Affymetrix GeneChip® Microarray Instrumentation System consisting of GeneChip® 3000Dx scanner with autoloader, FS450Dx fluidics station and

GCOSDx software is intended to measure fluorescence signals of labeled DNA and RNA target hybridized to GeneChip® arrays.

2. Special Condition for use Statement(s):

For use with separately cleared GeneChip microarray assays

H. Substantial Equivalence Information:

1. Predicate device name(s) and 510(k) numbers:

Affymetrix GeneChip Microarray Instrumentation System (k042279)

2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate
Technology Specifications	Same Same	Same Same
Differences		
Item	Device	Predicate
Indications for use	The Affymetrix GeneChip® Microarray Instrumentation System consisting of GeneChip® 3000Dx scanner with autoloader, FS450Dx fluidics station and GCOSDx software is intended to measure fluorescence signals of labeled DNA and RNA target hybridized to GeneChip® arrays.	The Affymetrix GeneChip® Microarray Instrumentation System consisting of GeneChip® 3000Dx scanner with autoloader, FS450Dx fluidics station and GCOSDx software is intended to measure fluorescence signals of labeled DNA target hybridized to GeneChip® arrays.

I. Standard/Guidance Document Referenced (if applicable):

Class II Special Controls Guidance Document: Instrumentation for Clinical Multiplex Test Systems: <http://www.fda.gov/cdrh/oivd/guidance/1546.html>

J. Performance Characteristics:

1. Analytical Performance:

a. Accuracy:

Not applicable – accuracy for each assay to be run on this system will be assessed during the clearance of the assay (k080896).

b. Precision/Reproducibility:

Subject of k042279

c. Linearity:

Not applicable – linearity for each assay to be run on this system will be assessed during the clearance of the assay (k080896)

d. Carryover:

Not applicable – linearity for each assay to be run on this system will be assessed during the clearance of the assay (k080896)

e. Interfering Substances:

Not applicable – carryover for each assay to be run on this system will be assessed during the clearance of the assay (k080896)

2. Other Supportive Instrument Performance Data Not Covered Above:

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.