March 15, 2018

Cancer Genetics, Inc.
Victoria Kusel
Senior Corporate Legal Associate
133 Southcenter Court
Morrisville, NC 27560

Re: K173839
Trade/Device Name: Tissue of Origin Test Kit-FFPE
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: OIW
Dated: December 15, 2017
Received: December 18, 2017

Dear Ms. Victoria Kusel:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Yun-fu Hu -S

for Reena Philip, Ph.D.
Director
Division of Molecular Genetics and Pathology
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173839

Device Name
Tissue of Origin Test Kit-FFPE

Indications for Use *(Describe)*

Indication for Use: The Cancer Genetics Tissue of Origin Test is an in vitro diagnostic intended to measure the degree of similarity between the RNA expression patterns in a patient's formalin-fixed, paraffin-embedded (FFPE) tumor and the RNA expression patterns in a database of fifteen tumor types (poorly differentiated, undifferentiated and metastatic cases) that were diagnosed according to then current clinical and pathological practice. This test should be evaluated by a qualified physician in the context of the patient's clinical history and other diagnostic test results.

Limitations: The Cancer Genetics Tissue of Origin Test is not intended to establish the origin of tumors (e.g., cancer of unknown primary) that cannot be diagnosed according to current clinical and pathological practice. It is not intended to subclassify or modify the classification of tumors that can be diagnosed by current clinical and pathological practice, nor to predict disease course or survival or treatment efficacy, nor to distinguish primary from metastatic tumor. Tumor types not in the Cancer Genetics Tissue of Origin Test database may have RNA expression patterns that are similar to patterns in the database. Therefore, results cannot be used to distinguish tumor types in the database from tumor types not in the database.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

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

The assigned Special 510(k) number is K173839.

Date Prepared: December 15, 2017

807.92 (a)(1):

Name: Cancer Genetics, Inc.
Address: 1640 Marengo Street
Los Angeles, CA 90033

Phone: (213) 863-0175
Contact: Janet A. Graff, Quality Assurance Manager
Fax: (323) 224-3096

807.92 (a)(2): Device Name – trade name and common name, and classification

Trade name: Cancer Genetics Tissue of Origin Test Kit-FFPE

Common name: Microarray, reagents and software system kit for gene expression-based diagnostics

Classification: 21 CFR § 862.3100, Amphetamine Test System
Class II

Product Code: OIW, Software, similarity score algorithm, tissue of origin for malignant tumor types

Panel: Toxicology (91)

807.92 (a)(3): Identification of the legally marketed predicate device

The Cancer Genetics Tissue of Origin Test Kit-FFPE as modified is substantially equivalent to the Pathwork Tissue of Origin Test Kit FFPE cleared under premarket notification K120489 on May 17, 2012 (which is substantially equivalent to the Pathwork Tissue of Origin Test Kit FFPE cleared under premarket notification K092967).

807.92 (a)(4): Device Description

The modified and the predicate devices (k092967 and k120489) are all in vitro diagnostic product consisting of a reagent kit and instructions, plus a microchip and software, for the comparison of the RNA expression pattern of a patient's tumor sample to a database of expression patterns of 15 known tumor tissues. Equipment required but not provided are an Affymetrix GeneChip Fluidics Station FS450Dx v2 and an Affymetrix GeneChip Scanner GCS3000Dx, attached to an Affymetrix Workstation with GeneChip Operating System (GCOS). Additional equipment required but not provided is commonly available laboratory equipment.

807.92 (a)(5): Intended Use

The Cancer Genetics Tissue of Origin Test is an in vitro diagnostic intended to measure the degree of similarity between the RNA expression patterns in a patient's formalin-fixed, paraffin-embedded (FFPE) tumor and the RNA expression patterns in a database of fifteen tumor types (poorly differentiated, undifferentiated and metastatic cases) that were diagnosed according to then current clinical and pathological practice. This test should be evaluated by a qualified physician in the context of the patient's clinical history and other diagnostic test results.

Limitations: The Cancer Genetics Tissue of Origin Test is not intended to establish the origin of tumors (e.g., cancer of unknown primary) that cannot be diagnosed according to current clinical and pathological practice. It is not intended to subclassify or modify the classification of tumors that can be diagnosed by current clinical and pathological practice, nor to predict disease course or survival or treatment efficacy, nor to distinguish primary from metastatic tumor. Tumor types not in the Cancer Genetics Tissue of Origin Test database may have RNA expression patterns that are similar to patterns in the database. Therefore, results cannot be used to distinguish tumor types in the database from tumor types not in the database.

807.92 (a)(6): Technological Similarities and Differences to Predicate

Comparison with Unmodified Device			
Feature/ component	**Tissue of Origin Test Kit-FFPE K092967**	**Tissue of Origin Test Kit-FFPE K120489**	**Modified Tissue of Origin Test Kit- FFPE**
		Substantially equivalent to K092967 cleared on May 17, 2012	
Intended use	The Pathwork Tissue of Origin Test is an in vitro diagnostic intended to measure the degree of similarity between the RNA expression patterns in a patient's formalin fixed, paraffin embedded (FFPE) tumor and the RNA expression patterns in a database of fifteen tumor types (poorly differentiated, undifferentiated, and metastatic cases) that were diagnosed according to then current clinical and pathological practice. This test should be evaluated by a qualified physician in the context of the patient's clinical history and other diagnostic test results.	Same	Same
Microarray	Pathchip®	Same chip, same location of all gene expression probes.	Same chip, same location of all gene expression probes.
Equipment			
	Hybridization oven	Same	Same
	Stain, wash	Same	Same
	Scanner	Same	Same
	Software	Same	Changed to Genechip™ System 3000 Dx v.2
Extraction	As described in K092967	Same	Same
Amplification	As described in K092967	Changed to: Allow a minimum of 30ng total RNA extracted from tissue specimen is required at a concentration of 10 ng/µI (± 0.5 ng/µI).	Changed to GeneChip™ 3' IVT Pico Kit
Purification of biotinylated cDNA	As Described in the Labeling in K092967	Changed, Added EtOH	Changed to GeneChip™ 3' IVT Pico Kit
Internal Processing Quality Control (Data Verification)	Percent Positive Overall Signal Regional Discontinuity	Same	Same
Software	FTP	Same	Same
Analysis	Algorithm as described in K092967	Same	Same
Report	Graphic presentation of Similarity Scores for fifteen tissues of origin	Same	Same

Comparison with Unmodified Device			
Feature/ component	**Tissue of Origin Test Kit-FFPE K092967**	**Tissue of Origin Test Kit-FFPE K120489**	**Modified Tissue of Origin Test Kit- FFPE**
Extraction Reagents	As K092967	Same	Same
Amplification Reagents	As K092967	Same	Changed to GeneChip™ 3' IVT Pico Kit
Analyte Detected on Chip	cDNA	Same	Same
Probes employed in test	2000	Same	Same
% Agreement with available diagnosis ("accuracy")	N= 462 (≥ 25 for each of 15 malignant tumor types). Agreement, 88.5% (85.3,91.3)	Percent agreement with result reported by original method, vs. reported by changed method. N=45, 3 per tissue attempted. 43 actually analyzed, I quality failure, 1 unusable because original test result with unavailable for comparison. Agreement, 99.7% (87.7, 99.9)	Percent agreement with result reported by original method, vs. reported by changed method. **1. Reagent Comparison:** N=142, randomly selected from the 15 subtypes Agreement, 90.8% (83.6, 95.3) **2. Software Comparison:** N=20, randomly selected Agreement, 100% (95.9, 100)

807.92 (b)(1): Brief Description of Non-clinical data

Two modifications were assessed (i) a change in the method and reagents for amplification and (ii) an update to the microarray processing software.

A set of randomly selected tumor specimens analyzed previously using the 510(k) cleared method, were also analyzed using the modified method, and the results were compared.

The modified method used GeneChip™ 3' IVT Pico Kit to perform target preparation while in the original 510(k) cleared method used the RampUp RNA amplification Kit. For this study, 142 specimens were selected from FFPE tumor specimens employed for assessment of performance during development of the original TOO-FFPE kit. The sample set included each of the tumor types in the database. Comparisons could be made for all 142 tumors. 133 of these were concordant and 9 were not, for a % concordance of 90.8% (95% confidence interval of 83.6%, 95.3%). The change was considered validated, because all pre-established criteria were met or exceeded.

Concordance in Tissue of Origin Test Results Between Paired Specimens Processed with the RampUp RNA Amplification Kit and the GeneChip™ 3' IVT Pico Kit							
		Concordance			**Discordance**		
Comparison	**# Specimens**	**Ratio**	**Percent**	**95% Confidence Interval**	**Ratio**	**Percent**	**95% Confidence Interval**
RampUp Versus Pico	142	133/142	90.8%	[83.6, 95.3]	9/142	9.2%	[5.7, 13.9]

The second modification to be assessed was the microarray processing software, which was upgraded from the Genechip™ System 3000 Dx (no longer supported by the manufacturer Affymetrix) to Genechip™ System 3000 Dx v.2 (FDA-cleared and CE marked for in vitro diagnostics use). For this study, 20 specimens were selected from reserves of FFPE tumor specimens employed for assessment of performance during development of the original TOO-FFPE kit and had also been analyzed using the GeneChip™ 3' IVT Pico Kit. For all 20 samples, the results were concordant between Dx and Dx v.2.

Concordance in Tissue of Origin Test Results Between Paired Specimens Processed with Dx Software and Dx v.2 Software							
		Concordance			**Discordance**		
Comparison	**# Specimens**	**Ratio**	**Percent**	**95% Confidence Interval**	**Ratio**	**Percent**	**95% Confidence Interval**
Dx Versus Dx v.2	20	20/20	100%	[95.9, 100]	0/20	0%	N/A

Conclusion: The minor software and reagent changes have not changed the performance of the Test.

807.92 (b)(2): Brief Description of Clinical Data

No clinical data is provided in this special 510(k).

807.92 (b)(3): Conclusions from Clinical Testing

No clinical testing was provided in this special 510(k)