K060627

510(k) SUMMARY

JUN - 7

1.0 Submitted By:

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2.0 Date Submitted

March 8, 2006

3.0 Device Name(s):

3.1 Proprietary Names: Tag-It™ Cystic Fibrosis Kit

3.2 Classification Names: CFTR (cystic fibrosis transmembrane conductance regulator) gene mutation detection system [866.5900]

4.0 Legally Marketed Device

Tag-It™ Cystic Fibrosis Kit claims substantial equivalence to the Tag-It™ Cystic Fibrosis Kit originally cleared under FDA 510(k) Number K043011

5.0 Device Description

Tag-It™ Cystic Fibrosis Kit includes the following components:

- Multiplex PCR Primer Mix including dNTPs designed to simultaneously produce 16 amplimers of the CFTR gene
- Multiplex ASPE Primer Mix including dNTPs (86 primers designed to hybridize to either wild-type or mutant alleles with proprietary sequences at their 5' ends designed to specifically hybridize to complementary sequences coupled to the bead component of the kit)
- Coupled Bead Suspension (86 spectrally distinguishable populations of 5.0 micron polystyrene beads internally dyed with red and infrared fluorochromes coupled to proprietary DNA sequences designed to specifically hybridize to complementary sequences on the ASPE primers)
- 10X Wash Buffer
- Tag-It™ Data Analysis Software (TDAS CF-I)

6.0 Intended Use

The Tag-It™ Cystic Fibrosis Kit is a device used to simultaneously detect and identify a panel of mutations and variants in the cystic fibrosis transmembrane conductance regulator (CFTR) gene in human blood specimens. The panel includes mutations and variants currently recommended by the American College of Medical Genetics and American College of Obstetricians and Gynecologists (ACMG/ACOG), plus some of the worlds most common and North American-prevalent mutations. The Tag-It™ Cystic Fibrosis Kit is a qualitative genotyping test which provides information intended to be used for carrier testing in adults of reproductive age, as an aid in newborn screening, and in confirmatory diagnostic testing in newborns and children.

The kit is not indicated for use in fetal diagnostic or pre-implantation testing. This kit is also not indicated for stand-alone diagnostic purposes.

7.0 Comparison to the Predicate (Description of the Modification to the Legally Marketed Device)

The Tag-It™ Cystic Fibrosis Kit performance parameters remain unchanged.

8.0 Summary of Performance Data

Performance data from validation testing supports equivalency.

Section 1: ADMINISTRATIVE INFORMATION

1.0 Submitted By:

Tm Bioscience Corporation
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Toronto, Ontario, M5G IY8
Canada

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2.0 Sponsor Address/FDA Registration Number

Tm Bioscience Corporation
439 University Ave., Suite 2000
Toronto, Ontario, M5G IY8
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Establishment Registration No. 3002777243

3.0 Product Name/Classification Name and Number

Proprietary Names
Tag-It™ Cystic Fibrosis Kit

Classification Names
CFTR (cystic fibrosis transmembrane conductance regulator) gene mutation detection system [866.5900]

4.0 Device Classification

FDA has classified clinical chemistry test systems of this type into Class II

5.0 Section 514 Compliance

This Special 510(k): Device Modification submission is prepared pursuant to the FDA publication: The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications Issue Date: March 20, 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN - 7 2006

Tm Bioscience Corporation
c/o Nancy Krunic, Ph.D.
Director, Clinical and Regulatory Affairs
439 University Ave
Toronto, Ontario M5G IY8
Canada

Re: k060627
Trade/Device Name: Tag-It™ Cystic Fibrosis Kit
Regulation Number: 21 CFR 866.5900
Regulation Name: CFTR (cystic fibrosis transmembrane conductance regulator) gene mutation detection system
Regulatory Class: Class II
Product Code: NUA
Dated: March 8, 2006
Received: March 15, 2006

Dear Dr. Krunic:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria Chan for
Dr Robert Becker

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K060627

Device Name: Tag-It™ Cystic Fibrosis Kit

Indications For Use:

The Tag-It™ Cystic Fibrosis Kit is a device used to simultaneously detect and identify a panel of mutations and variants in the cystic fibrosis transmembrane conductance regulator (CFTR) gene in human blood specimens. The panel includes mutations and variants currently recommended by the American College of Medical Genetics and American College of Obstetricians and Gynecologists (ACMG/ACOG), plus some of the worlds most common and North American-prevalent mutations. The Tag-It™ Cystic Fibrosis Kit is a qualitative genotyping test which provides information intended to be used for carrier testing in adults of reproductive age, as an aid in newborn screening, and in confirmatory diagnostic testing in newborns and children.

The kit is not indicated for use in fetal diagnostic or pre-implantation testing. This kit is also not indicated for stand-alone diagnostic purposes.

Maria M Chan
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K060627

Prescription Use _X_ and/or **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)