510K Number: K061979

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SEP 22 2006

Submitter: ImmuneTech Corporation
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Manufacturing Site: ImmuneTech Corporation
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Device Trade Name: MyAllergyTest ®
Device Common Name: Blood Sample Collection Kit
Device Classificiation: Class II
Device Product Code: JKA

Description of the modified device:

MyAllergyTest ® is a Sample Collection Kit containing the materials necessary to collect and mail a capillary blood sample to a clinical laboratory for allergen specific IgE profile testing. The device modification is to revise the limitations statement to allow testing of the whole blood sample for up to 30 days following collection. Currently the limitations states 10 days. No changes to the kit components.

Intended Use:

The MyAllergyTest ® is for the collection and transport of a capillary blood sample to a clinical laboratory for allergen specific IgE profile testing. The The MyAllergyTest ® is intended for use with the MyAllergyTest ® system (K020387). The MyAllergyTest ® is intended for home use by the lay consumer.

Proposed Labeling:
See attachment A

Summary of Device Testing:

Blood Sample Stability Studies were performed to obtain assurance that the whole blood sample would still provide an accurate assessment of allergen

specific IgE for the entire transport time indicated in the labeling (30 days). The results from these studies (Initial testing and validation results) confirmed that the sample would be stable during the indicated transport time. See attachment (s) B and C.

Summary of Design Control Activities:

- Risk Analysis- see attachment C
- Validation PROD-0011
- Declaration of conformity
- Project History file, not included in submission

Attachments:

Proposed Labeling, Attachment A (4 pages)
Initial Results, Attachment B (7 pages)
Validation Results, Attachment C (8 pages)
Risk Analysis, Attachment D (3 pages)
Completed Corrective Action Letter to the 483, Attachment E (1 page)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 2 2 2006

ImmuneTech Corporation
c/o Ms. Nancy Benson
VP Quality Systems
888 Oak Grove, Suite 4
Menlo Park, CA 94025

Re: k061979
Trade/Device Name: MyAllergyTest®
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: JKA
Dated: June 21, 2006
Received: July 13, 2006

Dear Ms. Nancy Benson:

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,

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

Indications for Use

510(k) Number (if known): K061979

Device Name: MyAllergyTest®

Indications For Use:

The MyAllergyTest® is for the collection and transport of a capillary blood sample to a clinical laboratory for allergen specific IgE profile testing. The MyAllergyTest® is intended for use with the MyAllergyTest® system. The MyAllergyTest® is intended for home use.

Prescription Use _____ AND/OR Over-The-Counter Use X

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Division Sign-Off

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

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K061979