7. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is being submitted in accordance with the requirements of The Safety Medical Device Act of 1990 and 21 CFR Part 807.92

510(k) Number: K021698

SEP 1 9 2002

Date of Summary Preparation:
May 14, 2002

Submitter: ImmuneTech Corporation
Contact Person: Vivianne Noetzel
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Manufacturing Site: ImmuneTech Corporation
Address: 888 Oak Grove, Suite 4
Menlo Park, CA 94025
Phone: 650-470-7420
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Device Trade Name: MyAllergyTest™
Device Common Name: Blood Sample Collection Kit
Device Classification: Class II (21 CFR 862.1675)
Device Product Code: JKA
Performance Standards: None established (as a medical device) under Section 514.

Device Description: 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.

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 MyAllergyTest™ is intended for use with the MyAllergyTest™ System (K020387). The MyAllergyTest™ is intended for home use by the lay consumer.

Indication 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 by the lay conusmer.

Substantial Equivalence Claim to:

Appraise-Cardio Sample Collection Kit K993787.

Summary of Device Testing:

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 (seven days). The results from these studies confirmed that the samples would be stable for the entire seven days.

Mailing Studies were performed to obtain assurance that the whole blood samples would still provide an accurate assessment of allergen specific IgE if sent by US Mail. The results from these studies confirmed that the samples would be stable when shipped using US Mail.

Consumer Studies were performed to obtain assurance that the general public would be able to obtain a blood sample by following the MyAllergyTest™ package insert. The results from these studies confirmed that the general public would be able to obtain a blood sample by following the MyAllergyTest™ package insert.

Consumer Comprehension Studies were performed to obtain assurance that the general public would be able to read and understand the MyAllergyTest™ package insert. The results from these studies confirmed that the general public would be able to read and understand the MyAllergyTest™ package insert.

Readability Studies were performed to assurance that the MyAllergyTest™ package was written at a 7th grade reading level. The results from the SMOG Readability Formula (NCCLS GP 14-A Labeling of Home-Use *In Vitro* Testing Products) confirmed that the MyAllergyTest™ package was written at a 7th grade reading level.

Conclusion:

These studies demonstrate the substantial equivalence of the MyAllergyTest™ to a currently marketed device that has been reviewed and cleared through the 510(k) notification process.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 19 2002

Ms. Vivianne Noetzel
ImmuneTech Corporation
P.O. Box 9433
Rancho Santa Fe, CA 92067

Re: k021698
Trade/Device Name: My Allergy Test™
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA
Dated: July 8, 2002
Received: August 23, 2002

Dear Ms. Noetzel:

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 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

6. INDICATIONS FOR USE STATEMENT

510(k) Number: K02 1698

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 by the lay consumer (Over-the-Counter).

Susan S. Alter

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021698

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

Concurrence of CDHR, office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use ✓
