Attachment B

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:	
Date of Summary Preparation:	January 24, 2002
Submitter:	ImmuneTech Corporation
	Contact Person: Vivianne Noetzel
	Address: P.O. Box 9433
	17394 Via Del Bravo
	Rancho Santa Fe, CA 92067
	Phone: 858-756-8483
	FAX: 858-759-7492
Manufacturing Site:	ImmuneTech Corporation
	Address: 888 Oak Grove, Suite 4
	Menlo Park, CA 94025
	Phone: 650-470-7420
	FAX: 650-470-7423
Device Trade Name:	MyAllergyTest™ System
Device Common Name:	Allergen Specific IgE Test System for the measurement of allergen specific IgE antibodies to Timothy Grass Bermuda Grass Mountain Cedar Short Ragweed Alternaria (Mold) Cat Dander Mite pternoyssinus Milk Egg White Wheat (food)
Device Classification:	Class II (21 CFR 866.5750)
Device Product Code:	82 DHB
Performance Standards:	None established (as a medical device) under Section 514.

Device Description:

MyAllergyTest™ System is a test for the measurement of allergen specific IgE in human serum. The MyAllergyTest™ System consist of two components:

1. MyAllergyTest™ System Reagents.
2. MyAllergyTest™ System support software for the Luminex $^{100™}$ I S Version 2.0

A serum sample is mixed with allergen specific coupled microspheres. If present, specific IgE in the sample will bind with the microspheres and form an allergen/sIgE complex. This complex is then sequentially incubated with biotin-labeled-anti-human IgE antibody and fluorescent-labeled-streptavidin. If specific IgE is present in the sample, the final sandwich complex of allergen/sIgE/biotin-anti-IgE/fluorescent-streptavidin will form. Measurement of the fluorescent signal from the sandwich complex is directly proportional to the concentration of allergen specific IgE in the sample. The MyAllergyTest System may only be run on the Luminex $^{100™}$ Integrated System Version 2.0. The MyAllergyTest™ System specific software for the Luminex $^{100™}$ Integrated System Version 2.0 will simultaneously measure and identify allergen specific IgE concentrations.

Intended Use:

The MyAllergyTest System is a quantitative in vitro diagnostic test for the measurement of allergen specific IgE antibodies in human serum samples. The MyAllergyTest System may only be run on the Luminex $^{100™}$ Integrated System Version 2.0. The MyAllergyTest™ System is intended for clinical laboratory use.

Indication for Use:
The MyAllergyTest™ System is a quantitative *in vitro* diagnostic test system used as an aid in the clinical diagnosis of IgE mediated allergenic disorders. Measurement of specific allergen antibodies may aid diagnosis of asthma, allergies, and other pulmonary disorders.
Substantial Equivalence Claim to: Pharmacia CAP System™ Specific IgE FEIA
Brief Description of Performance Data:
Studies were performed to evaluate the sensitivity, specificity, accuracy and precision of the MyAllergyTest™ System.

Study	Result
Sensitivity	88%
Specificity	94%
Accuracy	91%
Between Day Precision	5.6%
Within Day Precision	6.1%

RAST inhibition verified the immunological specificity of the IgE binding for each allergen.
Conclusion:
These studies demonstrate the substantial equivalence of the MyAllergyTest™ System to a currently marketed device that has been reviewed and cleared through the 510(k) notification process. They further demonstrate the suitability for use of the product for clinical laboratory professional use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Vivianne Noetzel
ImmuneTech Corporation
P.O. Box 9433
17394 Via Del Bravo
Rancho Santa Fe, California 92067

APR 17 2002

Re: k020387
Trade/Device Name: MyAllergyTest™ System
Regulation Number: 21 CFR § 866.5750
Regulation Name: Radioallergosorbent (RAST) Immunological Test System,
Regulatory Class: II
Product Code: DHB
Dated: January 31, 2002
Received: February 5, 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

INDICATIONS FOR USE STATEMENT

510(k) Number: K02 0387

Device Name: MyAllergyTest™ System

Indications for Use: The MyAllergyTest System is a quantitative in vitro diagnostic test for the measurement of allergen specific IgE antibodies in human serum samples. The MyAllergyTest System may only be run on the Luminex ^{100}™ Integrated System Version 2.0.

The MyAllergyTest™ System is used as an aid in the clinical diagnosis of IgE mediated allergenic disorders. Measurement of allergen specific IgE antibodies may aid diagnosis of asthma, allergies, and other pulmonary disorders.

Susan S. Alte...

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020387

(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 _____