MAY 22 2008

510(k) SUMMARY

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

The assigned 510(k) number is: K081217

1. *Name of Submitter, Contact Person and Date Summary Prepared:*

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Summary Prepared On: April 24, 2008

2. *Device Name:*

Trade/Proprietary Name:	HY•TEC™ Automated EIA System for Total IgE and Specific IgE
Common/Usual Name:	Enzyme Immunoassay System for Total and Specific IgE
Classification Name:	Radioallergosorbent (RAST) Immunological Test System

3. *Legally Marketed Equivalent Device Name:*

We are claiming substantial equivalence to the The HY•TEC™ Automated EIA System for Total IgE and Specific IgE, MCS Assay, cleared 510(k) K941278.

4. *Intended Use of the Device:*

The HY•TEC™ Specific and Total IgE EIA System is an enzyme immunoassay (EIA) method for the quantitative determination of allergen-specific and/or total IgE concentrations in human serum. The assay is to be used with the HY•TEC™ 288 instrument for in-vitro diagnostic use.

5. *Description of the Device:*

The HY•TEC 288 Automated EIA instrument is a fully-automated system, which performs sample dilution and pipetting, incubation, washing, reading and data analysis and prints reports. The new modified MCS (Modified Classification System) Specific/Total IgE assay includes the current set of five calibrators (100, 17.5, 3.5, 0.70 and 0.35 IU/mL) and a new zero calibrator.

The HY•TEC allergy system is standardized using anti-IgE discs and reference sera calibrated against WHO 2nd IRP 75/502 and offers a broad menu of specific allergens. The HY•TEC reagents have been optimized to provide a fast, sensitive sandwich immunoassay with a dynamic range from 0.05 to 100 IU/mL. An allergen-coated paper disc is incubated with a serum sample. Non-specific proteins are removed by washing and the disc is incubated with enzyme-labeled monoclonal anti human IgE conjugate. Following a second wash, substrate color is developed. The results are read spectrophotometrically against a calibration curve; results are reported in both IU/mL and Classes. The HY•TEC MCS Specific/Total IgE assay requires only three hours of total incubation time and completes assay runs within six hours for the maximum assay size of 288 tests.

6. *Device Comparison and Verification:*

Assay performance, including correlation with the predicate, analytical sensitivity, limit of detection, intra and inter assay precision, and dilution linearity demonstrate the acceptability of the zero calibrator.

7. *Conclusion:*

The modified device has the same technological characteristics and intended use and does not raise any new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Hycor Biomedical, Inc.
c/o Mr. P. Narayan Nayak
Director, Systems Development
7272 Chapman Ave.
Garden Grove, CA 92841

MAY 22 2008

Re: k081217
Trade/Device Name: HY•TEC™ Specific and Total IgE EIA System
Regulation Number: 21 CFR 866.5750
Regulation Name: Radioallergosorbent (RAST) immunological test system
Regulatory Class: Class II
Product Code: DHB, DGC
Dated: April 24, 2008
Received: April 30, 2008

Dear Mr. Nayak:

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). 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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

5.0 Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K081217

Device Name: HY•TEC™ Specific and Total IgE EIA System

Indications For Use:

The HY•TEC™ Specific and Total IgE EIA System is an enzyme immunoassay (EIA) method for the quantitative determination of allergen-specific and/or total IgE concentrations in human serum. The assay is to be used with the HY•TEC™ 288 instrument for in-vitro diagnostic use. Measurement of specific allergen antibodies and total IgE may aid in the diagnosis of asthma, allergies and other pulmonary disorders.

Prescription Use __X__ OR Over-The-Counter Use ____

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Maria M Chan

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K081217