NOV - 1 1999

K984433

CK-MB ASSAY

PREMARKET NOTIFICATION
[510(K)]

SAFETY AND EFFECTIVENESS SUMMARY
(ATTACHMENT)

1419 Energy Park Drive, St. Paul, Minnesota (612) 647-6370

Company Information

Quantech Ltd.
1419 Energy Park Drive
St. Paul, MN,
(612) 647-6370
Thomas Witty, Ph.D. - Vice President, Research and Development

Contact Information

Robin J. Hellen, M.S.
Hellen Professional Services
(818) 709-5646

Product Name

Classification Name:	Creatine Kinase (CK) or Isoenzymes Test Systems, Class II
Trade Name:	Quantech CK-MB Assay
Common Name:	CK-MB Test Kit

CLIA Categorization

We believe the Quantech CK-MB Assay to be moderately categorized based on previous classification of analogous tests.

Substantial Equivalence

The Quantech CK-MB Assay is substantially equivalent to the AxSYM® CK-MB assay marketed by Abbott Laboratories since 1993.

Intended Use

The *Quantech CK-MB Assay* is intended to be used as an aid in diagnosing myocardial infarction in patients exhibiting chest pain. It is intended to be used in conjunction with EKG, and physician examination, as well as possibly other biochemical blood tests to rule in or out origin of the chest pain.

Device Description

The Quantech CK-MB assay is based on the principle of two site, or sandwich immunoassay in combination with SPR surface mass measurement. Each test module contains a solid phase anti-CK-MB monoclonal antibody immobilized onto a gold surface. An anti-CK-MB polyclonal antibody, used to enhance the specific detection of the isoenzyme is introduced sequentially.

The Quantech assay utilizes CK-MB-specific antibody to capture the CK-MB in the sample. This is followed by a quantitation of the surface mass increase using surface plasmon resonance (SPR), to measure the CK-MB in plasma.

Comparison of Technological Characteristics

The Quantech CK-MB Assay is similar to the AxSYM® CK-MB assay as follows. Both assays are in vitro immunological assays for the quantitative measurement of human CK-MB. Additionally, both assays use antibody to CK-MB coated on a solid support, and both instruments utilize a microprocessor for instrument control, data acquisition, and data reduction.

Summary of Non-Clinical Performance Data

Dilution Linearity/Parallelism - The parallelism study was conducted to evaluate the linearity of the Quantech CK-MB Assay. Plasma samples were separately spiked with CK-MB and serially diluted with corresponding unspiked serum. The average percent of expected was 118%.

Recovery - Accuracy of the Quantech CK-MB Assay was calculated from test results as the percentage of added analyte, corrected for endogenous analyte, recovered by the assay. After correcting for endogenous CK-MB content, the average recovery was 103%.

Analytical Sensitivity - Multiple duplicates of zero samples (stripped plasma) were assayed to determine the minimum quantity of CK-MB detectable by the Quantech Assay. The average SPR signal shift plus two standard deviations (2 S.D.) was calculated and translated into a dose. The calculated analytical sensitivity of the Quantech CK-MB assay is 0.3 ng/mL.

Precision - The INTERASSAY precision was determined by evaluating three pools in triplicate on different days. The mean CK-MB concentrations (with % C.V.) were 37.5 (9.4%), 83.1 (4.8%), and 149 (7.0%) ng/mL for the low, medium and high pools, respectively.

TOTAL IMPRECISION was determined from the interassay data, and is a combination of results from multiple runs on multiple days. The mean CK-MB concentrations (with % C.V.) were 37.5 (13.3%), 83.1 (9.1%), and 149 (10.1%) ng/mL for the low, medium and high pools, respectively.

Summary of Non-Clinical Performance Data (Cont.)

Interfering Substances - Physiological interference was evaluated by spiking a plasma pool of CK-MB with hemoglobin, bilirubin and triglycerides at levels five to ten times the highest expected physiological concentration. The percent recovery of CK-MB was determined to be acceptable in all three solutions and no interference was noted by the endogenous substances in the Quantech CK-MB assay.

Hook Effect - Samples well beyond the standard curve range were assayed. No high dose hook effect was observed. Therefore, the Quantech CK-MB Assay does not give erroneously low results for grossly elevated samples up to at least 5,000 ng/mL.

Summary of Clinical Performance Data

Normal Range - Testing of apparently healthy individuals demonstrated that the Quantech CK-MB Assay and the predicate device perform similarly at and below the accepted value for cardiac damage (greater than 7.0 ng/mL CK-MB). Both methods are also compatible with published expected values. The 95% limit of normals as referenced in the predicate device insert is 3.8 vs. 6.5 ng/mL found herein, and 4.2 ng/mL found for the Quantech CK-MB assay. Both methods yielded a male mean which was higher than that of females, which is clinically characteristic of the CK-MB assay. Further demonstrating equivalence, samples containing high levels of either RF or HAMA assayed within the expected range on both methods.

The Quantech device demonstrates no false positive results with these apparently healthy individuals and is in 100% agreement with the predicate device.

Patient Sample Correlation - Results from human samples with values distributed throughout the quantitative range of the Quantech CK-MB, were compared with those obtained with a commercially available method (fluorogenic ELISA). The correlation coefficient was 0.95 (slope = 0.81, y-intercept = 0.37 ng/mL).

Conclusions Drawn From Performance Tests

The Quantech CK-MB Assay provides results which are internally accurate, unaffected by ordinary variation of sample matrix and equivalent to the results obtained using the approved device in a valid laboratory setting.

Additionally, both clinically-based studies (normal range, patient correlation) demonstrated essential equivalence between the two devices as measured by their correlation and the degree to which assay results are linearly related to one another over a broad range of values. Likewise, the normal range evaluation provided empirical evidence that the log of the assay value is statistically similar for both devices, and in agreement with published data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV - 1 1999

Quantech, Ltd.
c/o Ms. Robin J. Hellen, M.S.
Hellen Professional Services
9418 Lasaine Avenue
Northridge, California 91325

Re: K984433
Trade Name: Quantech CK-MB Assay
Regulatory Class: II
Product Code: MYT
Dated: August 30, 1999
Received: August 31, 1999

Dear Ms. Hellen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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

III. Statement for Indications for Use

510(k) Number (if known): K984433

Device Name: *Quantech CK-MB Assay*

Dean Cooper
(Division Sign-Off)
Division of Clinical Labora
510(k) Number K984433

Indications for Use:

The *Quantech CK-MB Assay* is intended to be used for the quantitative determination of the cardiac isoenzyme CK-MB, in order to assist in the diagnosis of acute myocardial infarction.

Concurrence of the CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ **OR** **Over the Counter Use:** _____