FEB 4 1998

K974839

FIRST MEDICAL, INC.

X 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Alpha Dx System

A. Name and Address of Submitter

- Company Name and Address: First Medical, Inc.
  530 Logue Avenue
  Mountain View, CA 94043
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- Contact Person: Van N. Johnson
- Date 510(k) summary was prepared: December 23, 1997

B. Device Names

1. Trade Names

   The ***Alpha Dx*** System consists of:

   - The ***Alpha Dx*** Analyzer, ***and***
   - The ***Alpha Dx*** Myo/CK/CK-MB/TnI Cardiac Panel Test Kit, ***or***
   - The ***Alpha Dx*** CK/CK-MB Panel Test Kit, ***or***
   - The ***Alpha Dx*** Myo/TnI Panel Test Kit

2. Common Names

   a. ***Alpha Dx*** Analyzer

   Fully integrated benchtop analyzer capable of performing *in vitro* diagnostic measurement of a panel of tests.

   b. ***Alpha Dx*** Panel Test Kits

   Rapid, quantitative and simultaneous measurement of myoglobin (Myo), creatine kinase (CK), creatine kinase MB isoenzyme (CK-MB) and cardiac troponin I (TnI) in whole blood or serum to aid in the diagnosis of acute myocardial infarction (AMI).

3. Classification Names

   a. ***Alpha Dx*** Analyzer

   Fluorescence Immunoassay Analyzer for use with the ***Alpha Dx*** Panel Test Kits for the rapid measurement of a panel of tests (Clinical Chemistry Panel Classification Device List).

b. ***Alpha Dx*** Panel Test Kits

Fluorescence Immunoassays for myoglobin, CK, CK-MB and TnI (Clinical Chemistry Panel and Immunology Classification Device List).

C. Legally Marketed Devices

1. Panel Test Kits
   - Dade Stratus Myoglobin Fluorometric Enzyme Immunoassay
   - Johnson & Johnson Vitros CK Slide
   - Dade Stratus CK-MB Fluorometric Enzyme Immunoassay
   - Dade Stratus Cardiac Troponin I Fluorometric Enzyme Immunoassay
   - Beckman Access Troponin I Immunoassay System
2. Analyzer
   - Dade Stratus II Fluorometric Immunoassay System

D. Device Description

The ***Alpha Dx*** Cardiac Panel Test Kits, when used with the ***Alpha Dx*** Analyzer, are fluorescence immunoassays for the rapid measurement of myoglobin, CK, CK-MB and TnI in human whole blood or serum.

E. Intended Use

The ***Alpha Dx*** Cardiac Panel Test Kit is intended for use with the ***Alpha Dx*** Analyzer to provide rapid, quantitative and simultaneous measurement of myoglobin, creatine kinase (CK), creatine kinase MB isoenzyme (CK-MB) and cardiac troponin I (TnI) in whole blood or serum to aid in the diagnosis of acute myocardial infarction (AMI). The Analyzer and Cardiac Panel Test Kit combine ease of use and rapid turnaround time with laboratory-quality performance and reliability. With factory calibration, built-in bilevel quality controls and closed tube sampling, the system can be used in the central laboratory, STAT lab, emergency department, coronary care unit, chest pain center and other point of care locations.

F. Comparison of Methodology with Predicate Devices

The ***Alpha Dx*** Cardiac Panel Test Kit, when used with the ***Alpha Dx*** Analyzer, provides quantitative determinations of human myoglobin, CK, CK-MB and TnI in whole blood or serum. The current Stratus Myoglobin, CK-MB and Troponin I Fluorometric Enzyme Immunoassays when used with the Stratus II Fluorometric System Analyzer, the Vitros CK Slides when used with the Vitros 700 and the Access Troponin I Assay when used with the Access Immunoassay System are examples of other devices currently marketed for the same uses.

The ***Alpha Dx*** Cardiac Panel Test Kits are two-site fluorescence immunoassays. The current Stratus Myoglobin, CK-MB and Cardiac Troponin I Fluorometric Enzyme Immunoassays and the Stratus II Fluorometric Immunoassay Analyzer are examples of currently available products that employ the immunofluorometric procedure and fluorometric detection.

Monoclonal and polyclonal antibodies are used in the ***Alpha Dx*** Cardiac Panel Test Kits. The use of monoclonal and polyclonal antibodies for immunoassay procedures has been clearly demonstrated in other currently commercially available assays and in numerous scientific reports.

G. Summary of Analytical Data

1. Dilution Recoveries

The mean recoveries by diluting serum samples with high myoglobin, CK, CK-MB or TnI are as follows:

Analyte	Myo	CK	CK-MB	TnI
Mean % Recoveries	92	97	103	99

Table 43 Dilution Recoveries

2. Analytical Sensitivity

The analytical sensitivity for the ***Alpha Dx*** myoglobin, CK, CK-MB and TnI assays are 1.1 ng/mL, 1.8 ng/mL, 0.04 ng/mL, 0.017 ng/mL, respectively.

3. Precision

Median %CV of the assays are as follows:

%CV	Myo	CK	CK-MB	TnI
Whole Blood Samples	3.9	5.3	3.9	7.3
Serum Samples	4.0	7.0	2.7	2.4

Table 44 Precision

H. Summary of Clinical Data

1. Correlation Between Paired Whole Blood and Serum Samples Tested with the *Alpha Dx* System

Paired whole blood and serum samples from serial draws of 72 chest pain patients and 24 healthy individuals were tested. Linear regression analyses, after exclusion of samples with levels outside the reportable ranges of the test methods, are as follows:

Method	Myo	CK	CK-MB	TnI
N	322	309	294	73
Slope	1.05	1.04	1.07	0.90
Intercept	-3	5	-0.1	0.08
r	0.99	0.99	1.00	0.99

Table 45 Correlation Between Whole Blood and Serum

2. Correlations Between Whole Blood Samples Assayed with the ***Alpha Dx*** System and Paired Serum Samples Assayed with the Predicate Methods

   The relation between myoglobin, CK, CK-MB and TnI measurements with the ***Alpha Dx*** System and the predicate devices was determined in serial samples from 410 chest pain patients and 134 healthy individuals, after exclusion of samples with levels outside the reportable range of the test methods. Results of the regression analyses are as follows:

	Myo	CK	CK-MB	TnI	TnI
Predicate	Stratus	Vitros	Stratus	Stratus	Access
N	955	923	676	226	244
Slope	0.81	0.77	1.07	0.18	1.44
Intercept (ng/mL)	-2	-1	1.1	0.56	0.96
r	0.98	0.97	0.97	0.93	0.88

Table 46 Correlation Between ***Alpha Dx*** System and Predicate Methods

3. Clinical Sensitivity and Specificity of the ***Alpha Dx*** TnI, Stratus TnI, Access TnI and Stratus CK-MB Assays

   The clinical cutoffs, sensitivity and specificity for the ***Alpha Dx*** TnI, Stratus TnI, Access TnI and the Stratus CK-MB are as follows:

Method	Cutoff Value (ng/mL)	Sensitivity (95% CI)	Specificity (95% CI)
Alpha Dx TnI	0.40	93 ± 6	94 ± 3
Stratus TnI	1.50	93 ± 6	93 ± 3
Access TnI	0.15	92± 6	88 ± 4
Stratus CK-MB	7.0	89± 7	90 ± 4

Table 47 TnI and CK-MB Sensitivity and Specificity Comparison

Sensitivity and specificity for the ***Alpha Dx*** TnI and Stratus CK-MB are comparable within the 95% confidence intervals of the two methods. The ***Alpha Dx*** TnI assay results were 92% concordant versus the Stratus CK-MB results in 362 subjects tested with both devices. McNemar's test indicates no statistically significant difference between the two assays in diagnostic performance.

I. Conclusion

The ***Alpha Dx*** Cardiac Test Discs are used with the ***Alpha Dx*** Analyzer for the rapid, quantitative and simultaneous measurement of myoglobin, creatine kinase (CK), creatine kinase MB isoenzyme (CK-MB) and cardiac troponin I (TnI) in whole blood or serum to aid in the diagnosis of acute myocardial infarction (AMI). The data shows that the ***Alpha Dx*** Cardiac Test Discs are substantially equivalent to other tests currently in commercial distribution for the purpose of analyzing unknown concentrations of myoglobin, CK, CK-MB and TnI.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 4 1998

Van N. Johnson
Vice President, Clinical and Regulatory Affairs
First Medical, Inc.
530 Logue Avenue
Mountain View, California 94043

Re: K974839
Alpha DX System
Regulatory Class: I, II
Product Code: MMI,JHX, DDR, CGX, KHO
Dated: December 23, 1997
Received: December 24, I997

Dear Ms. Johnson:

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 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/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

510(k) Number (if known): K974839

Device Name: _____

Indications For Use:

Statement of Indication for Use

The *Alpha Dx* Cardiac Panel Test Kit is intended for use with the *Alpha Dx* Analyzer to provide rapid, quantitative and simultaneous measurement of myoglobin, creatine kinase (CK), creatine kinase MB isoenzyme (CK-MB) and cardiac troponin I (TnI) in whole blood or serum to aid in the diagnosis of acute myocardial infarction (AMI). The Analyzer and Cardiac Panel Test Kit combine ease of use and rapid turnaround time with laboratory-quality performance and reliability. With factory calibration, built-in bilevel quality controls and closed tube sampling, the system can be used in the central laboratory, STAT lab, emergency department, coronary care unit, chest pain center and other point of care locations.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K974839

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)