DEC 1 8 2001

1.0 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

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

The assigned 510(k) number is: K012040

1. Establishment:

Response Biomedical Corp.
8855 Northbrook Court
Burnaby, British Columbia V5J5J1
Canada

Tel: (604) 681-4101
Fax: (604) 412-9830

Contact: William J. Radvak
President and CEO

Prepared: June 27, 2001

2. Trade Name: Response Biomedical Corp. RAMP™ Myoglobin Assay

Common Name: Myoglobin immunological test system

Classification Name: Myoglobin immunological test system

3. Predicate Device:

Immunoassay: Triage Cardiac Panel®; Myoglobin Assay (K973126) which is currently being marketed by Biosite Diagnostics, Inc.

Immunoassay: ACCESS® Myoglobin Assay (K000196) which is currently being marketed by Beckman Coulter, Inc.

4. Description of the Device:

The RAMP Myoglobin Assay is an immunochromatographic test for the quantitative determination of myoglobin in human EDTA whole blood, using the RAMP Reader.

Diluted EDTA whole blood is applied into the sample well of the Test Cartridge. The red blood cells are retained in the sample pad, and the separated plasma migrates along a strip, through a contact zone where it interacts with fluorescent latex particles. Latex (test) particles, coated with mouse monoclonal anti-myoglobin antibodies bind to myoglobin in the sample.

The sample moves by capillary action towards the end of the strip. As the sample migrates to the detection zone, myoglobin/anti-myoglobin particles are immobilized at the detection zone, and additional particles are immobilized at the internal control zone.

The RAMP Reader then measures the amount of fluorescence emitted by the complexes bound at the detection zone and at the internal control zone. Using a ratio between the two fluorescence values, a quantitative reading is calculated.

5. Comparison of Technological Characteristics

The RAMP Myoglobin Assay, Triage Cardiac Panel - Myoglobin; and ACCESS Myoglobin Assay are for the quantitative measurement of myoglobin in human whole blood (RAMP and Triage) or plasma (Triage and ACCESS). All three immunoassays utilize the binding of myoglobin to specific antibodies and utilize light in their respective detection systems. Both the RAMP and Triage assays measure light production from a fluorescence reaction using a fluorometer while the ACCESS Test measures light production from a chemiluminescent reaction using a luminometer. Both the RAMP Myoglobin and the Triage Cardiac Panel - Myoglobin are quantitative immunochromatographic tests, whereas the ACCESS Myoglobin test is an enzyme immunoassay.

6. Summary of Studies

PERFORMANCE CHARACTERISTICS

PRECISION : The intra-assay and the inter-assay precision of the RAMP Myoglobin Assay were determined by one operator assaying duplicates of each standard (50, 100 and 200 ng/mL myoglobin standards) twice each day over 10 days. The mean, standard deviation and % CV were calculated for the predicted myoglobin at each concentration. Within run precision ranged between 13.0 to 6.5%. Between run precision ranged from 9.1 to 13.8%. Total precision ranged from 10.6 to 14.3%.

LINEARITY: Discrete myoglobin antigen concentrations of 10, 50, 75, 100, 150, 200 and 350 ng/mL were prepared in bovine calf serum. The linearity is determined by assaying five replicates of each standard. The mean, standard deviation and % CV were calculated for the predicted myoglobin at each concentration. Linear regression analysis of expected myoglobin concentration versus actual myoglobin concentration results with an R = 0.998 and a slope of 1.07 with an offset of 1.143.

HOOK EFFECT: There is no high dose hook effect in the RAMP Myoglobin Assay up to the highest level tested (8000 ng/mL myoglobin).

ANALYTICAL SENSITIVITY: The lower limit of detection (LLD) is defined as the analyte concentration corresponding to the mean (n=20) plus 2 standard deviations of the zero. The LLD is 2.36 ng/mL myoglobin. Myoglobin levels in excess of 400 ng/mL are reported as greater than (>) 400 ng/mL.

ANALYTICAL SPECIFICITY: Samples containing rheumatoid factor at levels greater than 1300 Rf IU/mL may interfere with the test and cause erroneous results. If this occurs, another specimen should be obtained and tested by an alternate method.

INTERFERENCE: Potentially interfering substances were evaluated by spiking different concentrations of interferents in blood with 100 ng/mL of myoglobin added. Different blood samples were used for each interferent. Interference was evaluated by calculating the myoglobin concentration of interferent-spiked blood, expressed as a percentage of the myoglobin concentration of the unspiked (no interferent) blood sample. No evidence of cross-reactivity or interference was observed for hemoglobin (Hb), triglyceride, bilirubin, cholesterol, or coumidin at levels exceeding the highest expected physiological concentration of up to 2000 mg/dL, 3000mg/dL, 60 mg/dL, 2000 mg/dL, and 200 μg/mL, respectively. No trend was observed in the myoglobin predictions as the concentration of interferent was increased.

CLINICAL PERFORMANCE

EXPECTED VALUES

Whole blood samples from 196 healthy individuals, (92 males and 104 females) were assayed. The lower (LLN) and upper (ULN) limits for normal range were defined as the 5th and 95th percentile values, respectively. The normal range of the RAMP Myoglobin Assay was found to be from 19.15 ng/mL to 99.3 ng/mL in the normal population studied. Each laboratory should establish its own expected values.

PRECISION STUDY

Of 179 subjects tested in duplicate, 77 were normal individuals (40 males and 37 females) and 102 were suspected of acute myocardial infarct (AMI) based on the individual hospital criteria (63 males and 39 females). The samples were selected randomly from those obtained during the Method Comparison Study. The samples were stored refrigerated for up to five days between analyses. Data were winsorized (ACCESS values>400) to adjust for differing reportable ranges between the methods and two outliers excluded. Data are presented below:

Table 1-1

Population	n	Slope (y =)	Intercept	r
Patients with suspect AMI	102	0.9750x	1.9026	.986
Normal Individuals	77	0.9013x	3.7143	.967
Combined Populations	179	0.9702x	0.9349	.968

METHOD COMPARISON

Of the 415 subjects compared, 196 were normal individuals (92 males and 104 females) and 219 were patients suspected of AMI based on the individual hospital criteria (131 males and 88 females). An EDTA whole blood sample was obtained for each of these subjects. These samples were tested in RAMP Myoglobin Assay and results compared to those obtained with the Beckman ACCESS Myoglobin Assay. Data were winsorized (ACCESS results >400) to adjust for differing reportable ranges between the methods and three outliers excluded. Data are presented in Table 4-2 below. These results are comparable to correlations of the Biosite Triage Myoglobin Assay verses other clinical analyzers, (N=112) 1.25x+38.8; r=.943 and (N=108) 1.31x+17.0; r=.877.

Table 1-2

Population	n	Slope (y =)	Intercept	r
Patients with suspect AMI	219	1.0059x	29.576	.928
Normal Individuals	196	1.3831x	15.609	.889
Combined Populations	415	1.0309x	25.905	.932

7. Conclusion

The RAMP Myoglobin Assay when utilized with the RAMP Reader are substantially equivalent to other assays currently in commercial distribution for the measurement of myoglobin.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 1 8 2001

Mr. William Radvak
President and CEO
Response Biomedical Corp.
8855 Northbrook Court
Burnaby, B.C. V5J 5J1

Re: k012040
Trade/Device Name: RAMP™ Myoglobin Assay; RAMP Reader
Regulation Number: 21 CFR 866. 5680; 21 CFR 862.2560
Regulation Name: Myoglobin immunological test system; Fluorometer for clinical use
Regulatory Class: Class II; ~~Class 1~~
Product Code: DDR; KHO
Dated: October 30, 2001
Received: October 31, 2001

Dear Mr. Radvak:

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

2.0 STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K012040

Indications for Use: The RAMP Reader is a general use fluorometer that analyzes results produced by immunoassays that use a fluorophore having an excitation wavelength at 560 nm and an emission wavelength of 610 nm.

The RAMP™ Myoglobin Assay is an immunochromatographic test for the quantitative determination of myoglobin in human EDTA whole blood, using the RAMP Reader.

Jean Cooper for Jean Cooper
(Division Sign-Off)
Division of Clinical Labora... Devices
510(k) Number K012040

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)