DEC 2 2 2004

Section 3
quantex Myoglobin
510(k) Summary (Summary of Safety and Effectiveness)

Submitted by:

Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, MA 02421
Phone: 781-861-4467
Fax: 781-861-4207

Contact Person:

Carol Marble, Regulatory Affairs Director
Phone: 781-861-4467 / Fax: 781-861-4207

Summary Prepared:

October 28, 2004

Name of the device:

quantex Myoglobin

Classification name(s):

866.5680	Myoglobin Immunological Test System	Class II
DDR	Myoglobin, Antigen, Antiserum, Control	

Identification of predicate device(s):

K902154 N Latex Myoglobin (Dade Behring)

Description of the device/intended use(s):

Quantex Myoglobin is intended as a latex particle enhanced immunoturbidimetric assay for the quantitative determination of myoglobin concentration in human serum or plasma (EDTA or Lithium Heparin) on Clinical Chemistry Systems as an aid in the diagnosis of myocardial infarction. For *in vitro* diagnostic use.

Quantex Ferritin / Myoglobin controls I/II are intended for use in monitoring the quality control of results obtained with the quantex Myoglobin reagents by turbidimetry. (NOTE: These controls were previously FDA cleared for use with quantex Ferritin, reference K040879.) For *in vitro* diagnostic use.

Quantex Myoglobin standard multipoint is intended for use in establishing the calibration curve for the quantex Myoglobin reagents by turbidimetry. For *in vitro* diagnostic use.

Statement of Technological Characteristics of the Device Compared to Predicate Device:

Quantex Myoglobin is substantially equivalent to the commercially available predicate device, N Latex Myoglobin, in performance and intended use.

Summary of Performance Data:

In a method comparison study evaluating 67 samples with myoglobin levels ranging from 16 to 2070 ng/ml on an ILab 600, the slope was 0.99 and the correlation coefficient (r) was 0.999 for quantex Myoglobin versus the predicate device.

Within run precision assessed over multiple runs using quantex Ferritin/Myoglobin controls I/II on an ILab 600 gave a CV of 1.1% (at a mean of 71.4 ng/ml) and 1.3% (at a mean of 229 ng/ml).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 22 2004

Ms. Carol Marble
Regulatory Affairs Director
Instrumentation Laboratory Company
101 Hartwell Avenue
Lexington, MA 02421-3125

Re: k042982
Trade/Device Name: quantex Myoglobin
Regulation Number: 21 CFR 866.5680
Regulation Name: Myoglobin immunological test system
Regulatory Class: Class II
Product Code: DDR, JIT, JJX
Dated: October 28, 2004
Received: October 29, 2004

Dear Ms. Marble:

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and 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 (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Cornelia B. Rooks

Cornelia B. Rooks, MA
Acting Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K042982

Device Name: quantex Myoglobin

Indications for Use:

Quantex Myoglobin is intended as a latex particle enhanced immunoturbidimetric assay for the quantitative determination of myoglobin concentration in human serum or plasma (EDTA or Lithium Heparin) on Clinical Chemistry Systems as an aid in the diagnosis of myocardial infarction. For *in vitro* diagnostic use.

Quantex Ferritin / Myoglobin controls I/II are intended for use in monitoring the quality control of results obtained with the quantex Myoglobin reagents by turbidimetry. (NOTE: These controls were previously FDA cleared for use with quantex Ferritin, reference K040879.) For *in vitro* diagnostic use.

Quantex Myoglobin standard multipoint is intended for use in establishing the calibration curve for the quantex Myoglobin reagents by turbidimetry. For *in vitro* diagnostic use.

Prescription Use ✓ (Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K042982