DEC 1 9 2003

K032663

Section 3
quantex CRP High Sensitivity
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:

August 27, 2003

Name of the Device:

quantex CRP High Sensitivity
quantex CRP High Sensitivity standard multipoint
quantex CRP High Sensitivity controls 1/2

Classification Name(s):

866.5270	C-Reactive Protein Immunological Test System	Class II
DCK	C-Reactive Protein, Antigen, Antiserum, and Control	

Identification of predicate device(s):

K991385 N *High Sensitivity* CRP

Description of the device/intended use(s):

Quantex CRP High Sensitivity is intended as a latex particle enhanced immunoturbidimetric assay for the quantitative determination of C-Reactive Protein (CRP) in human serum on Clinical Chemistry Systems. C-Reactive Protein (CRP) aids in detecting and evaluating infection, tissue disorder, inflammatory disorders and associated diseases.

When a sample containing CRP is mixed with the Latex Reagent and the Reaction Buffer included in the kit, the coated latex particles agglutinate. The degree of agglutination is directly proportional to the concentration of CRP in the sample and is determined by measuring the decrease of transmitted light caused by the aggregates.

Quantex CRP High Sensitivity standard multipoint is intended for use in establishing the calibration for the quantex CRP High Sensitivity reagents by turbidimetry.

Quantex CRP High Sensitivity controls 1/2 are intended for use in monitoring the quality control of results obtained with quantex CRP High Sensitivity reagents by turbidimetry.

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

quantex CRP High Sensitivity is substantially equivalent to the commercially available predicate device (N *High Sensitivity* CRP) in performance and intended use.

Section 3 (Cont.)
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Summary of Performance Data:

Method Comparison

In method comparison studies evaluating 156 samples with CRP levels ranging from 0.18 to 283 mg/L on an ILab 900/1800 and 55 samples ranging from 0.20 to 283 mg/L on an ILab 600, the slope and correlation coefficient (r) for quantex CRP High Sensitivity versus the predicate device are shown below:

IL System	Slope	Intercept	r
ILab 900/1800	0.948	-0.105	0.9969
ILab 600	0.957	-0.074	0.9989

Precision

Within run precision assessed over multiple runs using two levels of control with the following results:

ILab 900/1800	Mean mg/L CRP	Within run CV%	Total CV%
quantex CRP High Sensitivity control 1	2.39	1.25	3.32
quantex CRP High Sensitivity control 2	5.87	0.88	1.50

ILab 600	Mean mg/dL CRP	Within run CV%	Total CV%
quantex CRP High Sensitivity control 1	2.32	2.11	2.50
quantex CRP High Sensitivity control 2	5.82	1.96	2.09

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 1 9 2003

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

Re: k032663
Trade/Device Name: quantex CRP High Sensitivity
Regulation Number: 21 CFR 866.5270
Regulation Name: C-reactive protein immunological test system
Regulatory Class: Class II
Product Code: DCK; JIS; JJX
Dated: November 21, 2003
Received: November 24, 2003

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,

Steven I. Gutman, M.D., M.B.A.
Director
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): K032663

Device Name: quantex CRP High Sensitivity

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol C Benson for Jean Cooper, DVM

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032663

Prescription Use ✓ **OR** Over-The-Counter Use _____
(Per 21 CFR 801.019)