MAY 1 0 2004

K040879

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

Submitted by:

Instrumentation Laboratory Company
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Lexington, MA 02421
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Contact Person:

Carol Marble, Regulatory Affairs Director
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Summary Prepared:

April 2, 2004

Name of the device:

quantex Ferritin

Classification name(s):

866.5340	Ferritin Immunological Test System	Class II
DBF	Ferritin, Antigen, Antiserum, Control	

Identification of predicate device(s):

K935847 AxSYM Ferritin

Description of the device/intended use(s):

Quantex Ferritin is intended as a latex particle enhanced immunoturbidimetric assay for the quantitative determination of ferritin in human serum or EDTA plasma on Clinical Chemistry Systems, and aids in the diagnosis of diseases affecting iron metabolism, such as hemochromatosis (iron overload) and iron deficiency anemia.

The quantex Ferritin controls I/II are intended for use in monitoring the quality control of results obtained with the quantex Ferritin reagents by turbidimetry.

The quantex Ferritin standard multipoint is intended for use in establishing the calibration curve for the quantex Ferritin reagents by turbidimetry.

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

Quantex Ferritin is substantially equivalent to the commercially available predicate device, AxSYM Ferritin, in performance and intended use.

Summary of Performance Data:

In a method comparison study evaluating 94 serum samples with Ferritin levels ranging from 3.2 to 1000 ng/ml on an ILab 900/1800, the slope was 0.92 and the correlation coefficient (r) was 0.994 for quantex Ferritin versus the predicate device.

Within precision assessed over multiple runs using quantex Ferritin controls I/II on an ILab 900/1800 gave a CV of 4.1% (at a mean of 43.2 ng/mL) and 1.6% (at a mean of 402.8 ng/mL).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 1 0 2004

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

Re: k040879
Trade/Device Name: Quantex Ferritin
Regulation Number: 21 CFR 866.5340
Regulation Name: Ferritin immunological test system
Regulatory Class: Class II
Product Code: DBF, JJX, JIT
Dated: May 03, 2004
Received: May 04, 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).

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,

Joseph L. Hackett

Joseph L. Hackett, Ph.D.
Acting Director
Division of Immunology and Hematology Devices
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): K040879

Device Name: quantex Ferritin

Indications for Use:

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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)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K040879