K990234

JUL - 9 1999

Qualisys
Diagnostics, Inc.

510(k) Summary

Qualisys PSA Immunoassay

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

1. Submitter name, address, contact

Qualisys Diagnostics, Incorporated
16 Technology Drive, Suite 118
Irvine, CA 92618

Telephone: (949) 788-0633
Fax: (949) 788-0623

Contact Person: Grace Kwan

Date Prepared: May 19, 1999

2. Device name

Proprietary name: Qualisys PSA Immunoassay

Common name: Chemiluminescense assay for the determination of Prostate-Specific Antigen (PSA).

Classification Name: Prostate-Specific Antigen (PSA) for Management of Prostate Cancers

3. Predicate device

Abbott IMx® PSA
(P910007)

4. Device description

The Qualisys PSA Immunoassay is a two-site chemiluminescense assay.

- 1st incubation: 15 minutes at room temperature. Specimen, control or calibrator [100 µL] and PSA Antibody Solution [100 µL] react to form a sandwich complex.
- 2nd incubation: 2 minutes at room temperature. Streptavidin-coated paramagnetic particle solution [25 µL] is added to the reaction mixture. After the 2-minute incubation, the sandwich complex is bound to the solid-phase via the interaction of biotin and streptavidin.
- Removal of unbound materials: The paramagnetic particles are washed four times with wash buffer [1.0 mL/wash] to remove unbound materials.

Device description (continued)

- Re-suspension of paramagnetic particles: Deionized (DI) water [25 µL] is added to re-suspend the washed paramagnetic particles.
- Substrate addition and detection: Chemiluminogenic substrate [50 µL] is added to the solid-phase bound complex and results in "glow" chemiluminescence, which is measured using a luminometer (photomultiplier). Emission of light is quantified for 1 second, and is expressed in relative light units (RLU).
- The amount of bound labeled antibody in RLU's is directly proportional to the concentration of PSA in the sample. Results are determined using cubic spline immunoassay curve fitting.

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5. Intended use

The Qualisys PSA Immunoassay is a paramagnetic particle immunoassay intended for the *in vitro* quantitative determination of prostate-specific antigen (PSA) in human serum. The Qualisys PSA Immunoassay is further indicated for the serial measurement of PSA as an aid in the prognosis and management of patients with prostate cancer.

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6. Comparison to predicate device

The Qualisys PSA Immunoassay is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Abbott IMx® PSA.

The following tables compare the Qualisys PSA Immunoassay with the predicate device, Abbott IMx® PSA:

Similarities:

• Assay Methodology:	Sandwich immunoassay
• Sample Type:	Serum
• Storage Condition:	2-8 °C
• Label	Alkaline Phosphatase
• Detector:	Photomultiplier Tube (PMT)

Comparison to predicate device (continued)

Differences:

Feature	Qualisys PSA	Abbott IMx® PSA
Intended Use	For the *in vitro* quantitative determination of PSA in human serum. It is further indicated for the serial measurement of PSA as an aid in the prognosis and management of patients with prostate cancer.	For the quantitative measurement of PSA in human serum: 1) as an aid in the detection of prostate cancer when used in conjunction with DRE in men aged 50 years or older. Prostatic biopsy is required for diagnosis of cancer; 2) as an adjunctive test used as an aid in the management of prostate cancer patients.
Sample Volume	100 µL	150 µL
Assay Range	0 to 50 ng/mL	0 to 100 ng/mL
Temp. Control	Not Required (Room Temperature)	Required
Instrument Required	Zylux Luminometer	Abbott IMx® Analyzer
Test Processing	Manual (A liquid handling system may be use to assist in the pipetting of multiple samples.)	Automated
Control Levels	2	3
Calibration Levels	5	6
Capture Antibody	Monoclonal	Polyclonal
Solid-phase	Streptavidin-coated paramagnetic particles	Monoclonal Anti-PSA coated microparticles
Substrate	ImmuGlow™ (Indoxyl -3-phosphate and lucigenin)	4-Methylumbelliferyl Phosphate
Detection	Chemiluminescense	Fluorescence
Data Analysis	External software: cubic spline for curve fitting and data reduction	Internal data reduction via microcomputer
Calibration	Full calibration curve with every run	Full calibration curve every 4 weeks

Comparison to predicate device (continued)

Performance Characteristics:

Feature	Qualisys PSA	Abbott IMx® PSA
Precision	ng/mL PSA	ng/mL PSA
Intra-assay	Low (0.52) 3.4% Med (3.05) 1.7% High (23.06) 3.0%	Low (4.6) 3.5% Med (15.6) 3.3% High (60.2) 3.1%
Inter-assay	Low (0.52) 5.7% Med (3.05) 2.6% High (23.06) 3.7%	Low (4.6) 4.7% Med (15.6) 4.5% High (60.2) 5.3%
Analytical Sensitivity	0.003 ng PSA/mL	0.1 ng PSA/mL
Functional Sensitivity	0.1 ng PSA/mL	Not reported
Spike Recovery	90 to 110%	91 to 103%
Dilution Recovery	92 to 108%	Not reported
Method Comparison	versus Abbott IMx® PSA: n = 108 Range of values (Abbott): 0 to 46.83 ng PSA/mL Range of values (Qualisys): 0 to 42.30 ng PSA/mL $y = 0.9955x + 0.5185$ (Least Squares) $r^2 = 0.9747$ $s^2_{slope} = 0.000243$ $s^2_{y\text{-intercept}} = 0.067012$	
Interfering Substances	No interference up to:	No interference up to:
Bilirubin	49 mg/dL	25 mg/dL
Hemoglobin	600 mg/dL	600 mg/dL
IgG	1900 mg/dL	250-2900 mg/dL
PAP	1000 ng/mL	1000 ng/mL
Protein	13 g/dL	3-13 g/dL
Triglycerides	2730 mg/dL	3000 mg/dL
Cyclophosphamide	700 µg/mL	700 µg/mL
DES	2 µg/mL	2 µg/mL
Doxorubicin HCl	16 µg/mL	16 µg/mL
Methotrexate	30 µg/mL	30 µg/mL
Megestrol Acetate	90 µg/mL	90 µg/mL
Flutamide	10 µg/mL	10 µg/mL
Lupron	100µg/mL	100µg/mL
High Dose Hook Effect	No high dose hook effect up to 1250 ng/mL	Not reported

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL -9 1999

Ms. Grace Kwan
Director, Quality and Regulatory Affairs
Qualisys Diagnostics, Inc.
16 Technology Drive, Suite 118
Irvine, California 92618

Re: K990234
Trade Name: Qualisys PSA Immunoassay
Regulatory Class: II
Product Code: LTJ
Dated: May 19, 1999
Received: May 20, 1999

Dear Ms. Kwan:

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 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). 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/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

Attachment 4

Indications for Use Statement

510(k) Number K990234

Device Name Qualisys PSA Immunoassay

Indications for Use

The Qualisys PSA Immunoassay is a paramagnetic particle immunoassay for the *in vitro* quantitative determination of prostate-specific antigen (PSA) in human serum. The Qualisys PSA Immunoassay is further indicated for the serial measurement of PSA as an aid in the prognosis and management of patients with prostate cancer.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IS NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K990234

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