

M E T R I K A

Metrika, Inc.
510 Oakmead Parkway
Sunnyvale, CA 94086
main 408 524 2255
fax 408 524 2252

510(k) SUMMARY

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 K991532.

807.92 (a)(1): Name: Metrika, Inc.
Address: 510 Oakmead Parkway
Sunnyvale, CA 94086
Phone: (408) 524-2255
FAX: (408) 524-2252
Contact: Stephen J. Hardt

807.92 (a)(2): Device name- trade name and common name, and classification

Trade name (Device): DRx[®] Qt. hCG
Common Name (Device): whole blood hCG immunoassay system
Classification (Device): 21 CFR 862.1155

Trade name (Control): DRx[®] Qt. hCG Control Set
Common Name (Control): assayed hCG control

Classification (Control): 21 CFR 862.1660

807.92 (a)(3): Identification of the legally marketed predicate device

(Device)

DRx[®] Qt. hCG is substantially equivalent to the commercially available predicate device, Stratus[®] βhCG (Dade Behring Inc., Miami, FL). DRx[®] Qt. hCG reports a single result without additional off-line dilutions or whole blood specimen manipulations. Stratus[®] requires dilutions of samples greater than 1000 mIU/mL and sample centrifugation (for plasma) prior to evaluations in order to report the final result.

(Control)

Name: Dade[®] Immunoassay Controls Comprehensive Tri-Level
Manufacturer: Dade International, Inc.

807.92 (a)(4): Device Description

(Device)

The DRx[®] Qt. hCG device is a single-use, disposable four-channel reflectance photometer integrated with dry reagent chemistry strips and contained within a sealed plastic case. Each unit consists of:

- an optics subassembly that also supports the reagent strips
- a printed circuit board that includes a microprocessor, analog electronics, battery clips, batteries, silicon diode photodetectors, and light emitting diodes (LEDs)
- a plastic molded part (“spider”) that supports the liquid crystal display (LCD), the sample pad and the auto start leads, and also provides optical shielding
- two reagent strips
- whole blood separation chemistry pad
- a desiccant
- liquid crystal display (LCD)

Both test strips are lateral flow immunoassays for measuring hCG between zero and 10,000 mIU/mL. In both strips, a blue color is measured in discrete test zones. The test zones are the areas where the specific reactions occur and concentrations are measured.

The whole blood separation mechanism occurs when the whole blood sample reaches the sample pad and immobilizes the red blood cells. As a result, the plasma freely migrates by capillary action onto the assay strips to complete the final reactions. The hCG reaction proceeds as follows: anti-hCG antibody, conjugated to blue microparticles, migrate across the strip upon the addition of whole blood sample. The amount of blue microparticles captured on the test zones is proportional to the amount of hCG in the sample.

The LEDs and silicon photodetectors compare the reflectances of the color intensities before and after the sample addition. Based on the calibration parameters stored in memory, the numerical concentrations of hCG is calculated. The final assay results are expressed in mIU/mL hCG.

(Control)

The DRx[®] Qt. hCG Control Set is a bovine plasma-based, liquid, 2-level control set to be used in quality control procedures with the DRx[®] Qt. hCG test. The assayed control set is used for evaluating precision and systematic analytical deviations that may arise from device variations.

807.92 (a)(5): Intended use

(Device)

The DRx[®] Qt. hCG is a rapid, single-use, point-of-care device for the quantitative measurement of human chorionic gonadotropin (total β hCG) in capillary and venous whole blood. The device is for professional use as an aid in the assessment of pregnancy status.

(Control)

The DRx[®] Qt. hCG Control Set is a two level, assayed, liquid control containing human chorionic gonadotropin for the evaluation of precision and accuracy of the DRx[®] Qt. hCG device.

807.92 (a)(6): Technological Similarities and Differences to the Predicate

Similarities Between DRx[®] Qt. hCG and Stratus[®] β hCG

CHARACTERISTIC	DRx[®] Qt. hCG	Stratus[®] βhCG K850570
Intended Use	DRx [®] Qt. hCG is a rapid, single-use, point-of-care device for the quantitative measurement of human chorionic gonadotropin (total β hCG) in capillary and venous whole blood samples. The device is for professional use as an aid in the assessment of pregnancy status.	The Stratus β hCG Fluorometric Enzyme Immunoassay is for quantitative determination of total beta human chorionic gonadotropin (β hCG) levels in serum and plasma for the detection of pregnancy.
Analyte(s)	hCG (mIU/mL) WHO 3 rd IS 75/537	hCG (mIU/mL) WHO 3 rd IS 75/537
Testing Matrix (Specimen Type)	Plasma (after integrated red blood cell separation)	Serum and plasma
Testing Environment	professional use	professional use
Risk to Patient	not a sole discriminant; hCG results are interpreted along with medical histories and other diagnostic procedures.	not a sole discriminant; hCG results are interpreted along with medical histories and other diagnostic procedures.

807.92 (a)(6): Technological Similarities and Differences to the Predicate (continued)

Differences Between DRx[®] Qt. hCG and Stratus[®] βhCG

CHARACTERISTIC	DRx[®] Qt. hCG	Stratus[®] βhCG K850570
Methodology/Testing Platforms	DRx [®] Qt. hCG is a four channel, reflectance photometer (plus an internal reference channel) with integral dry chemistry strips.	Stratus [®] βhCG is a Fluorometric Enzyme Immunoassay.
Reportable Ranges	5 to 10,000 mIU/mL	2 to 1000 mIU/mL
Dilutions	Not required	Required for samples greater than 1000mIU/mL hCG
Specimen Processing	Not required (straight addition of whole blood specimen into device for testing)	Required (centrifugation of whole blood specimen to obtain serum or plasma before testing)

807.92 (a)(6): Technological Similarities and Differences to the Predicate (continued)

**Similarities Between DRx[®] Qt. hCG Control Set
and Dade[®] Immunoassay Controls Comprehensive Tri-Level**

CHARACTERISTIC	DRx[®] Qt. hCG Control Set	Dade[®] Immunoassay Controls Comprehensive Tri-Level K860906
Intended Use	The DRx [®] Qt. hCG Control Set is a two level, assayed, liquid control containing human chorionic gonadotropin for the evaluation of precision and accuracy of the DRx [®] Qt. hCG device.	Dade [®] Immunoassay Controls Comprehensive Tri-Level are intended to assist in monitoring accuracy and precision in clinical assays.
Testing Environment	professional use	professional use
Test Method	quantitative	quantitative

**Differences Between DRx[®] Qt. hCG Control Set
and Dade[®] Immunoassay Controls Comprehensive Tri-Level**

CHARACTERISTIC	DRx[®] Qt. hCG Control Set	Dade[®] Immunoassay Controls Comprehensive Tri-Level K860906
Analyte(s)	hCG	(Various constituents), e.g. Acetaminophen Lidocaine Digoxin TSH Vitamin B12 hGH FSH PSA hCG hLH, etc.
Matrix	Liquid, bovine plasma-based matrix with spiked human-based analyte	Lyophilized, human source materials

The differences in the two testing platforms for either devices or control materials do not raise new issues of safety and effectiveness.

807.92 (b)(1): Brief Description of Nonclinical Data (Device)

Studies were conducted that evaluated hCG for analytical sensitivity, analytical specificity, and linearity.

Sensitivity studies demonstrated that the device is sensitive to 5 mIU/mL hCG.

DRx[®] Qt. hCG results were not affected by the addition of potential interferents such as biological compounds and therapeutic agents found routinely in blood. In addition, DRx[®] Qt. hCG results were not affected by potential cross/reactants similar to alpha hCG homology such as hLH, hFSH, and hTSH. The device is specific for total beta hCG subunit present as intact hCG or free beta subunit.

Linearity studies confirmed dynamic ranges of 5 to 10,000 mIU/mL for hCG.

807.92 (b)(2): Brief Description of Clinical Data (Device)

Accuracy was evaluated by comparative testing between DRx[®] Qt. hCG and Stratus[®] βhCG as the predicate method. Ninety-six (96) venous whole blood samples were assayed by DRx[®] Qt. hCG among four "POL" clinical sites and in-house, and by the predicate method. In addition, 63 matched whole blood capillary (fingerstick) samples were collected at the clinical sites. These fingerstick samples were compared to venous samples tested in DRx[®] Qt. hCG assay to demonstrate equivalence of sample. The data are summarized below (predicate method = X-axis).

CLINICAL LINEAR REGRESSION DATA

	n samples	Linear Regression Equation	Correlation Coefficient
hCG (venous compared to predicate)	96	$y = 0.92x + 20$	0.98
hCG (fingerstick compared to predicate)	63	$y = 1.05x + 8$	0.96
hCG (DRx[®] venous vs. DRx[®] fingerstick)	63	$y = 1.06x - 6$	0.99

Precision was evaluated at three sites by repeat testing of a 3-level whole blood precision panel (low, middle, and high hCG levels) on a single day. The coefficients of variation ranged from 8.3% to 15.1% across the three sites.

807.92 (b)(3): Conclusions from Nonclinical and Clinical Testing (Device)

Studies demonstrated substantial equivalence between DRx[®] Qt. hCG and an existing product already being marketed in terms of accuracy and precision. Sensitivity and linearity studies confirmed the assay's reportable range, and interference substance studies confirmed the assay's specificity.



DEPARTMENT OF HEALTH & HUMAN SERVICES

SEP 17 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Ya-Chen Hsu
Clinical Research Associate
Metrika, Inc.
510 Oakmead Parkway
Sunnyvale, California 94086

Re: K991532
Trade Name: DRx[®] Qt. hCG
Regulatory Class: II Product code: DHA
Regulatory Class: I reserved Product Code: JJX
Dated: July 20, 1999
Received: July 21, 1999

Dear Mr. Hsu:

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.

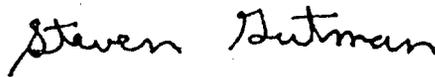
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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 I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K991532

Device Name: DRx[®] Qt. hCG

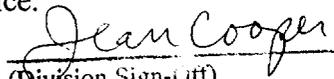
INDICATIONS FOR USE

DRx[®] Qt. hCG is a rapid, single-use, point-of-care device for the quantitative measurement of human chorionic gonadotropin (total β hCG) in capillary and venous whole blood samples. The device is for professional use as an aid in the assessment of pregnancy status.

Device Name: DRx[®] Qt. hCG Control Set

INDICATIONS FOR USE

The DRx[®] Qt. hCG Control Set is a two level, assayed, liquid control containing human chorionic gonadotropin for the evaluation of precision and accuracy of the DRx[®] Qt. hCG device.



(Division Sign-Off)
Division of Clinical Laboratory Devi-
510(k) Number K 991532

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)