MAR 1 8 2004

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 501(k) number is: K033297.

Submitted by: *ZBx* Corporation
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Contact Person: Tracy Yang, Manager of Quality and Regulatory Affairs

Date of Summary: October 10, 2003

Proprietary Name: ZAP™ hCG Test

Common or Classification Name: Human Chorionic Gonadotropin (hCG) Test System

Predicate Device: ICON® II HCG ImmunoConcentration Assay marketed by Beckman Coulter, Inc.

Device Description: The ZAP™ hCG Test is a one-step immunochromatographic assay for the rapid qualitative detection of hCG in human serum, plasma or whole blood.

Intended Use: An immunoassay used for the qualitative detection of human chorionic gonadotropin in human serum, plasma or whole blood and is indicated as an aid for health care professionals in the diagnosis of early pregnancy.

Comparison of Characteristics of the ZAP™ hCG Test with the Predicate Device:

	ICON® II HCG Assay (Predicate Device)	ZAP™ hCG Test
Indications for Use	Determination of hCG in urine or serum (The product insert discusses hCG as a marker for the early detection of pregnancy)	Qualitative detection of hCG in whole blood, plasma or serum to aid in the diagnosis of early pregnancy
Intended Users	Health care professionals	Health care professionals
Assay Format	Flow-through immunoassay	Chromatographic immunoassay
Detector Antibody	Monoclonal antibody to hCG is linked to alkaline phosphatase	Monoclonal antibody to hCG is linked to colloidal gold
Assay Indicators	Positive Control/Reference Zone Negative Control Zone Test Spot	Control Band Test Band
Specimen	450 µL of urine or serum	35 µL of whole blood, plasma or serum
Test Procedure	Multi-step, multiple reagent addition test	One-step, no reagents required
Complexity	Sample is added to the test cylinder, enzyme-linked hCG antibody is added to the cylinder and allowed to react. Unbound antibody is washed away; substrate solution is added to the cylinder and allowed to react. Adding wash solution stops the color reaction.	Sample is added to the test and allowed to react.
Analytical Sensitivity	Urine: 20 mIU/mL Serum: 10 mIU/mL	Whole blood, plasma, serum: 10 mIU/mL

Agreement with Predicate Device:	A total of 116 serum samples were tested and compared to the results obtained with the predicate device. The results of the two assays were in agreement except for four samples that were positive for hCG by the predicate device only. The discrepant samples were quantitated with the Beckman Access® Total β-hCG assay and the concentrations were in the range 2-6 mIU hCG/mL. Therefore, they were correctly reported as negative based on the 10 mIU hCG/mL cut-off value of the ZAP™ hCG Test.
Performance Data:	A number of evaluation studies were carried out on the ZAP™ hCG Test to determine the functional effectiveness of the test. Results of these studies included: (1) no interference from potentially interfering substances (albumin at 14 g/dL, bilirubin at 30 mg/dL, haemoglobin at 250 mg/dL, triglycerides at 2000 mg/dL); (2) no cross-reactivity to LH at 500 mIU/mL, FSH at 1000 mIU/mL, or TSH at 1000 μIU/mL; (3) >90% correlation of results from whole blood and plasma near the cut-off value; and (4) 100% agreement in a blind hCG study using spiked whole blood and involving three health care sites.
Conclusion:	The ZAP™ hCG Test performs as well as the ICON® II HCG ImmunoConcentration Assay legally marketed by Beckman Coulter Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Ms. Tracy Yang
Manager of Quality and Regulatory Affairs
ZBX Corporation
42 Laird Drive
Toronto,
CANADA M4G 3T2

Re: k033297
Trade/Device Name: ZAP™ hCG Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: JHI
Dated: February 17, 2004
Received: February 18, 2004

Dear Ms. Yang:

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,

Jean M. Cooper, MS, D.V.M.

Jean M. Cooper, MS, D.V.M.
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

510(k) Number (if known): K033297

Device Name: ZAP™ hCG Test

Indications For Use:

The ZAP™ hCG Test is an immunoassay used for the qualitative detection of human chorionic gonadotropin in human whole blood (capillary and heparinized venous), plasma, or serum and is indicated as an aid for health care professionals in the diagnosis of early pregnancy.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/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) K033297