

MAY 28 1998

**510(k) SUMMARY**  
**ICON<sup>®</sup> F<sub>x</sub> hCG Immunochemical Test for hCG**

**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: \_\_\_\_\_.**

**Developed by:** SKD, Inc. A Beckman Coulter Company  
1050 Page Mill Road, Bldg. 2B  
Palo Alto, CA USA 94303-0105  
Attention: Karen L. Richards, Manager, Clinical  
and Regulatory Affairs  
Phone: (650) 845-3434, Fax (650) 845-3540

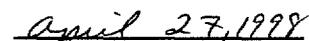
**Manufactured by:** Beckman Coulter San Diego  
8958 Terman Court  
San Diego, CA USA 92196-9006

**Proprietary name:** ICON<sup>®</sup> F<sub>x</sub> hCG

**Classification name:** Human Chorionic Gonadotropin Test System

**Predicate Device:** ICON<sup>®</sup> II HCG ImmunoConcentration<sup>™</sup>  
Assay

  
**Karen L. Richards**  
**Manager, Clinical and Regulatory Affairs**

  
**Date**

### **510(k) SUMMARY (continued)**

- Device Description:** The ICON® F<sub>x</sub> hCG test uses two distinct monoclonal antibodies specific to the alpha and beta subunits of hCG to provide a test capable of detecting hCG concentrations as low as 20 mIU/mL urine and 10 mIU/mL serum (IU=International Units).
- Intended Use:** A rapid qualitative test designed to detect human chorionic gonadotropin (hCG) in urine or serum, as an aid in the early detection of pregnancy.
- Labeling:** Labeling is provided in this 510(k) for multiple configurations of the ICON® F<sub>x</sub> hCG test. The urine-serum test differs from the urine test only by labeling; all materials in the Test Card remain the same across the multiple configurations.

**510(k) SUMMARY (continued)**

**Comparison of ICON<sup>®</sup> II HCG and ICON<sup>®</sup> F<sub>x</sub> hCG Test Systems**

	<b>ICON<sup>®</sup> II HCG (Predicate Device)</b>	<b>ICON<sup>®</sup> F<sub>x</sub> hCG</b>
<b>Indications for Use</b>	An ImmunoConcentration <sup>™</sup> Assay for the Determination of human chorionic gonadotropin (hCG) in urine or serum. (Summary and Explanation section of the product instructions discusses hCG as a marker for the early detection of pregnancy.)	A rapid, qualitative test designed to detect human chorionic gonadotropin (hCG) in urine or serum, as an aid in the early detection of pregnancy.
<b>Used by</b>	Health professionals	Health professionals
<b>Principles of the Test</b>	ImmunoConcentration <sup>™</sup> Assay utilizing two specific mouse monoclonal antibodies to the alpha and beta subunits of the hCG molecule for the detection of intact hCG.	Immunochromatographic Assay utilizing the same two specific mouse monoclonal antibodies to the alpha and beta subunits of the hCG molecule as the ICON <sup>®</sup> II HCG test, for the detection of intact hCG.
<b>Test Procedure</b>	Multi-step, multiple reagent addition test.	One-step, no reagents required.
<b>Method of Detection</b>	Visual detection; no instrumentation required.	Visual detection; no instrumentation required.

**510(k) SUMMARY (continued)**

**Comparison of ICON® II HCG and ICON® F<sub>x</sub> hCG Test Systems  
 (continued)**

	<b>ICON® II HCG (Predicate Device)</b>	<b>ICON® F<sub>x</sub> hCG</b>
<b>Chemical/ Biological Safety</b>	Universal biological safety precautions for sample handling should be observed. Some reagents contain 0.1% sodium azide, and must be disposed of using universal precautions.	Universal biological safety precautions for sample handling should be observed.
<b>Internal Controls</b>	<p>1) Positive Control/Reference Zone: With serum, the amount of color reaction present on the Test spot may be compared to the color reaction present on the Control/Reference spot, for a semi-quantitative interpretation at 25 mIU hCG/mL. For urine and serum, a positive Control/Reference zone demonstrates that the reagents were working properly.</p> <p>2) Negative Control Zone: Identifies nonspecific immunological binding or insufficient washing. If color develops in the negative control zone, the test is invalid.</p>	<p>1) Positive Procedural Control: Demonstrates that sample was added correctly and the detection reagents were working properly.</p> <p>2) Negative Control: A second line appearing in the Test Window, indicating the presence of human anti-mouse antibodies in the test sample. Appearance of this second line indicates an invalid test result.</p> <p>3) Flow Indicator: Blue color developing in the Flow Indicator window indicates that sample was added properly and flowed down the test strip.</p>

**510(k) SUMMARY (continued)**

**Comparison of ICON® II HCG and ICON® F<sub>x</sub> hCG Test Systems  
 (continued)**

	<b>ICON® II HCG (Predicate Device)</b>	<b>ICON® F<sub>x</sub> hCG</b>
<b>Limit of Detection</b>	Urine: 20 mIU hCG/mL Serum: 10 mIU hCG/mL	Urine: 20 mIU hCG/mL Serum: 10 mIU hCG/mL
<b>Specificity</b>	No reaction with homologous hormones hLH, hFSH, hTSH – urine and serum	No reaction with homologous hormones hLH, hFSH, hTSH – urine; hLH, hFSH, hTSH, hPL and hGH - serum
<b>Complexity</b>	Sample is added to the test cylinder, enzyme-linked 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 reaction.	Sample is added to the Sample Pad. The test card is closed, and reactions take place.

Additionally, the high level of agreement in the multi-center clinical trial testing supports the substantial equivalence of these two test kits. For both urine and serum samples, the overall level of agreement was greater than 99.5% (See **Tab 8**).



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

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• Manager, Clinical and Regulatory Affairs  
SKD, Inc.  
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Palo Alto, California 94303-0105

Re: K981512  
ICON® F<sub>x</sub> hCG Immunochemical Test for hCG  
Regulatory Class: II  
Product Code: JHI  
Dated: April 27, 1998  
Received: April 28, 1998

Dear Ms. Richards:

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 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.

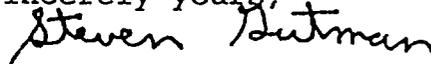
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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/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

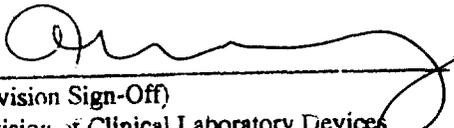
Enclosure

### Indications for Use Statement

510(k) Number (if known): \_\_\_\_\_

Device Name: ICON® F<sub>x</sub> hCG Immunochemical Test for hCG

Indications for Use: The ICON® F<sub>x</sub> hCG test is a rapid qualitative test designed to detect human chorionic gonadotropin (hCG) in urine or serum, as an aid in the early detection of pregnancy. The ICON® F<sub>x</sub> hCG test is for professional use.

  
(Division Sign-Off)  
Division of Clinical Laboratory Devices

510(k) Number 12981512

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

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_