

**FEB 3 2000**

### 510(k) Summary

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

The assigned 510(k) number is K994227

1. Date of summary: January 31, 2000
2. Submitted by: Advantage Diagnostics Corporation  
2440 Leghorn Street Mountain View CA, 94043
3. Device Name: Advantage hCG Test (Urine/Serum)
4. Device Classification: Class II, 862.1155 Product Code JHI
5. Device description: The Advantage hCG Test (Urine/Serum) is an immunochromatographic based one step *in vitro* test.
6. Intended Use: The test is designed for the qualitative detection of hCG in human urine and serum as an early indication of pregnancy. This test is for use in clinical laboratories by health care professionals.
7. Substantial Equivalence: The Advantage hCG Test (Urine/Serum) was found substantially equivalent to the PS-Unit Cassette/Serum and Urine Combo HCG manufactured by International Newtech Development, Inc. Both products are immunoassays and use specific antibodies to detect the hCG in human urine and serum. The sensitivity of the tests are similar, the Advantage hCG Test detects hCG in serum and urine, at 20ng/mL or greater while the predicate device detects hCG in serum and urine at concentrations greater than 20ng/mL. The tests demonstrated 100% correlation when 100 serum (51 positive and 49 negative) and 105 urine samples (40 positive and 65 negative) from pregnant and non pregnant women were evaluated and compared. The tests are similar in sensitivity, specificity and accuracy.

**Conclusion:**

The Advantage hCG Test (Urine /Serum) and the PS-Unit Cassette/Serum and Urine Combo HCG are substantially equivalent in performance characteristics. The correlation of the two tests was 100%.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

**FEB 3 2000**

Ms. Janis Freestone  
Director, Regulatory Affairs  
Advantage Diagnostics Corporation  
2440 Leghorn Street  
Mountain View, California 94043

Re: K994227  
Trade Name: Advantage hCG Test (Urine/Serum)  
Regulatory Class: II  
Product Code: JHI  
Dated: December 3, 1999  
Received: December 15, 1999

Dear Ms. Freestone:

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.

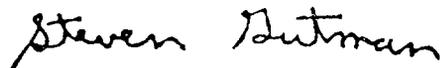
A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (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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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" (21CFR 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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large initial 'S' and 'G'.

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

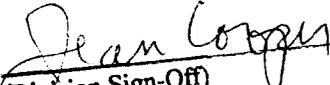
Enclosure

510k Number: K994227

Device Name:  
Advantage hCG Test (Urine/Serum)

Indications for Use:

The Advantage hCG Test (Urine/Serum) is a qualitative, rapid immunochromatographic assay used to detect the presence of hCG in human urine and serum for the early detection of pregnancy. The test is intended for use in clinical laboratories by health care professionals.

  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K 994 227

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use              
(Per 21 CFR 801.109)

OR

Over the counter use