

JUN 25 1998

K981838

510(k) Notification
Unotech Diagnostics Inc.
AccuStrip™ hCG-Urine
May 21, 1998

**510(k) Summary of Safety and Effectiveness
Substantial Equivalence Discussion**

Trade or Proprietary Name: AccuStrip™ hCG-Urine
Common or Usual Name: Human Chorionic Gonadotropin Test System
Product Classification No.: 21 CFR §862.1155, Class II
Manufacturer: Unotech Diagnostics Inc.
2235 Polvorosa Avenue, Suite 220
San Leandro, CA 94577
Contact Person: Ken Wu, Ph.D.
President
Phone: (510) 352-3070

We conducted a multicenter clinical study in three physicians' offices laboratories. We provided each site with the Unotech AccuStrip™ hCG-Urine and the Unotech AccuTest™ hCG-Urine.

A total of 208 urine specimens were tested in these physicians' office laboratories using both Unotech tests. Clinical subjects included female patients seeking confirmation of pregnancy, those who were confirmed pregnant, and 19 post-menopausal women.

The test results show that the Unotech AccuStrip™ hCG-Urine has 100% agreement with the Unotech AccuTest™ hCG-Urine.

	Unotech AccuStrip™ hCG-Urine	Unotech AccuTest™ hCG-Urine
Positive	89	89
Negative	119	119

35

The following experiments were carried out to evaluate the sensitivity of AccuStrip™ hCG-Urine at low end and high end levels of hCG. Urine samples with hCG concentrations of 0, 25, 50, 10², 10³, 10⁴, 10⁵, 5x10⁵ and 10⁶ mIU/mL were tested. The results are presented below.

hCG (mIU/mL)	0	25	50	10 ²	10 ³	10 ⁴	10 ⁵	5x10 ⁵	10 ⁶
# of samples	10	10	10	10	10	10	10	10	10
Positive	0	10	10	10	10	10	10	10	10
Negative	10	0	0	0	0	0	0	0	0

The results demonstrate that the Unotech AccuStrip™ hCG-Urine Test can detect hCG in urine at levels as low as 25 mIU/mL and as high as 1,000,000 mIU/mL.

These results establish that the Unotech AccuStrip™ hCG-Urine Test is substantially equivalent to the AccuTest™ hCG-Urine Test.

The intended use of the Unotech AccuStrip™ hCG-Urine is for the early detection of pregnancy by the qualitative determination of human chorionic gonadotropin (hCG) in human urine. Our intent is to market this product to physicians' office laboratories and clinical laboratories in the U.S.A. as well as in the foreign countries.



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 25 1998

Ken Wu, Ph.D.
• President
Unotech Diagnostics, Inc.
2235 Polvorosa Avenue, Suite 220
San Leandro, California 94577

Re: K981838
Unotech AccuStrip™ hCG-Urine
Regulatory Class: II
Product Code: JHI
Dated: May 21, 1998
Received: May 26, 1998

Dear Dr. Wu:

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.

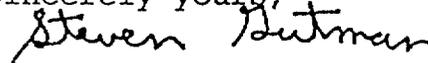
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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/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 (if known): N/A

Device Name: AccuStrip hCG-Urine

Indications For Use:

The intended use of the Unotech AccuStrip hCG-Urine is for the qualitative determination of human chorionic gonadotropin (hCG) in human urine for the early detection of pregnancy. We intend to market this product to physicians' office laboratories and clinical laboratories in the U.S.A. as well as in the foreign countries.



(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K981838

(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 _____

(Optional Format 1-2-96)