

3/9/99

K990576



**Wyntek**  
diagnostics

510k OSOM Card Pregnancy Test

Wyntek  
Diagnostics  
Inc.

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ISO9001  
EN46001  
Certified

6146  
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diagnostics.  
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**8. 510 (k) Summary**

Submitter : Wyntek Diagnostics, Inc.  
6146 Nancy Ridge Dr. Ste. 101  
San Diego, CA 92121  
Tel: 619-452-3198  
Fax: 619-452-3258

Contact Person: Shu-Ching Cheng

**Product Name:**

Proprietary Name:	OSOM® Card Pregnancy Test
Common Name:	OTC Pregnancy Test Kit
Classification Name:	Kit, Test, Pregnancy, HCG, OTC
Classification Number:	75LCX

**Intended Use:** OSOM® Card Pregnancy Test is a pregnancy test intended for home use.

**Description:** OSOM® Card Pregnancy Test uses color immunochromatographic technology with antibodies coated on the membrane. If hCG is present in urine, a blue test line will appear to indicate a positive result.

**Substantial Equivalence:** OSOM® Card Pregnancy Test is substantially equivalent to Warner-Lambert e.p.t Pregnancy Test and Carter Wallace FIRST RESPONSE Pregnancy Test. All these tests utilize immunochromatographic technology and anti-hCG antibodies to detect hCG in urine. All three tests interpret the results through the development of the color lines.

**Precision:** OSOM® Card Pregnancy Test, when compared to a professional hCG test, OSOM® Classic hCG Urine Test, with a total of 217 urine specimens, results in a sensitivity of 99.1% and a specificity of 100%. Also, a consumer testing was conducted. Of the 74 participants' results evaluated against their clinical status, OSOM® Card Pregnancy Test gave an overall agreement of 100%.

Applicant Signed: Shu-Ching Cheng Date: March 3, 1999  
Shu-Ching Cheng



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Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Mr. Shu-Ching Cheng  
Vice President of Operations  
Wyntek Diagnostics, Inc.  
6146 Nancy Ridge Drive, Suite 101  
San Diego, California 92121

Re: K990576  
Trade Name: OSOM® Card Pregnancy Test  
Regulatory Class: II  
Product Code: LCX  
Dated: February 22, 1999  
Received: February 23, 1999

Dear Mr. Cheng:

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.

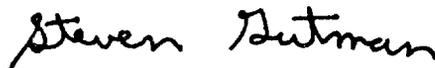
A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration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

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

**2. Device Indications For Use**

510 (k) Number: TBD     K990576

Device Name: **OSOM® Card Pregnancy Test**

**Indication For Use:**

The OSOM® Card Pregnancy Test is intended for the qualitative determination of human chorionic gonadotropin, hCG, in urine for early detection of pregnancy for home use.

Sean Cooper  
 (Division Sign-Off)  
 Division of Clinical Laboratory Services  
 510(k) Number: K990576

\_\_\_\_\_  
 Division Sign-Off  
 Division of Clinical Laboratory Services  
 510(k) Number: \_\_\_\_\_

(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 ✓