

1001-4325250 17.00
K973879
OSOM Card hCG 510 (K)



wyntek
diagnostics

NOV - 4 1997

8. 510 (k) Summary

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Contact Person: Shu-Ching Cheng

Product Name:

Proprietary Name: OSOM™ Card hCG-Urine Test
Common Name: hCG Urine Pregnancy Test Kit
Classification Name: Human chorionic gonadotropin (hCG)
test
Classification Number: 75JHI

Intended Use: The OSOM Card hCG-Urine Test is intended for the qualitative determination of human chorionic gonadotropin (hCG) in urine for early detection of pregnancy. FOR LABORATORY AND PROFESSIONAL IN VITRO USE ONLY.

Description: OSOM Card hCG-Urine Test uses color immunochromatographic technology with antibodies coated on the membrane. If hCG is present in urine, a red test line in Result Window will appear to indicate a positive result.

Substantial Equivalence: OSOM Card hCG-Urine Test is substantially equivalent to Quidel RapidVue hCG Test and Abbott TestPack Plus hCG Urine Test. All three 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: The OSOM Card hCG-Urine Test, when compared to Abbott TestPack Plus hCG Urine Test with a total of 227 urine specimens, results in a sensitivity of 100% and a specificity of 100%. Also, an evaluation of the OSOM Card hCG-Urine Test was conducted at three physicians offices. Each site tested the randomly coded panel consisting of negative, low positive and moderate positive samples for three days. The results obtained had 100% agreement with the expected results

Applicant Signed: Shu-Ching Cheng Date: Oct 28, 1997
Shu-Ching Cheng



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

NOV - 4 1997

Re: K973879
Trade Name: OSOM™ Card hCG-Urine Test
Regulatory Class: II Tier: II
Product Code: JHI
Dated: September 9, 1997
Received: September 10, 1997

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 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 requirement, 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.

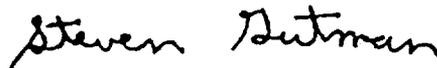
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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 at (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

2. Device Indications For Use

510 (k) Number: K973879

Device Name: OSOM™ Card hCG-Urine Test

Indication For Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


 (Division Sign-Off)
 Division of Clinical Laboratory Devices
 510(k) Number K973879

Prescription Use
(Per 21 CFR 801.109)

OR Over-The-Counter Use