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Medical Diagnostic Devices. Contract R&D. OEM
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510(K) Summary (K984076)

Submitter

Name and address: Alfa Scientific Designs, Inc.
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San Diego, CA 92121
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Contact Person: Naishu Wang, MD, Ph.D.

Date Prepared: 12/30/98

Device Name

Trade Name: Instant-ViewTM Pregnancy Urine Test

Common Name: Human Chorionic Gonadotropin (hCG) Test

Classification name: 21CFR section 862.1155, Class II.
A Qualitative Human Chorionic
Gonadotropin (hCG) test system.

Predicate device

The Instant-ViewTM Pregnancy Urine Test is substantially equivalent to other legally marketed devices for the similar intended use. The device used for comparison study is OSOM Pregnancy Urine Test made by Wyntek Diagnostic, Inc., 510K#: K953383.

Device description

A single step, visually read, qualitative chromatographic immunoassay, single use cassette test

Intended use

The Instant-ViewTM Pregnancy Urine Test is designed for qualitative detection of the human chorionic gonadotropin (hCG) in urine. The test is for use as an aid in the diagnosis of early pregnancy.

Continued on next page

Summary of the similarities to the predicate device

- The intended use and performance characteristics:
Both devices are intended to use for an early detection of hCG in human urine at the level close to 25 mIU/ml (OSOM claimed a sensitivity to hCG as low as 30 mIU/ml) or greater (calibrated against the WHO 3rd IS 75/537).
- Technological characteristics:
Both devices are one step, qualitative, visual lateral flow immuno-Chromatographic test in a sandwich complex format of anti-hCG antibody /hCG/ anti-hCG antibody.
- Interpretation of results:
The presence of C line serves as an internal quality control, and the presence of the T line indicates a positive result.

Discussion and Conclusion

- The accuracy by correlation of the results from the Instant-ViewTM Pregnancy Urine Test and the legally marketed test is 100%, indicating that the Instant-ViewTM Pregnancy Urine Test is substantially equivalent to this existing legally marketed product.
 - The evaluation results from a clinical lab and three physician's offices conducted by the persons with diverse educational backgrounds and working experience agreed 100% with the results expected.
 - Based on the results of the correlation and POL studies, we may conclude that the Instant-ViewTM Pregnancy Urine Test is as safe, as effective, and performs as well as the legally marketed device. Therefore, this test is suitable for use by health care professionals with diverse educational backgrounds and work experience.
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 16 1999

Naishu Wang, M.D., Ph.D.
President
Alfa Scientific Designs, Inc.
11494 Sorrento Valley Road, Suite F&M
San Diego, CA 92121

Re: K984076
Trade Name: Instant-View Pregnancy Urine Test
Regulatory Class: II
Product Code: 75 JHI
Dated: January 6, 1999
Received: January 11, 1999

Dear Dr. Wang:

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.

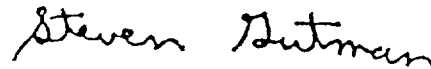
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

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): K 984076

Device Name: Instant-View
pregnancy Urine Test

Indications For Use:

The Instant-View Pregnancy Urine Test is a qualitative immunoassay for the detection of human chorionic gonadotropin (hCG) in urine for the early detection of pregnancy.

This test is for laboratory and professional use only.

[Signature]
(Division Sign-Off)
Division of Clinical Laboratory
510(k) Number K 984076

(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)