K023037

APR 0 9 2003

Advanced Diagnostics, Inc.

510 (k) Summary

Submitter

Name and address Advanced Diagnostics, Inc.
(Division of Inamco Group of Companies)
801 Montrose Avenue
S. Plainfield
NJ 07080
908 754 4880 (Tel)
908 754 5181 (Fax)

Contact Person: Dr. D. M. Chouhan

Date Prepared: 11 September 2002

Device name:

Trade Name: Mid Stream Pregnancy Test

Common Name: Human Chorionic Gonadotropin (hCG) Test

Classification Name: 21 CFR section 862.1155, Class II. - A qualitative Human Chorionic Gonadotropin (hCG) test system.

Predicate Device

The Mid Stream Pregnancy Test is substantially equivalent to other legally marketed devices for the similar intended use. The device used for comparison study is Acon Midstream Pregnancy Test made by Acon Laboratories, Inc. having a 510K #.K983090.

Device Description

A single step, visually read, qualitative immuno-chromatographic single use stick test.

Intended Use

The Mid Stream Pregnancy test is a home pregnancy urine test 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.....2

801 Montrose Avenue, S. Plainfield, NJ 07080 USA Tel: 908 754 4880 Fax: 908 754 5181
e mail : cs@inamco.com

Summary of the Similarities to the Predicate device

- The intended use and performance characteristics : Both devices are OTC devices intended to use for an early detection of hCG in human urine.
- 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 comparison studies demonstrated that there was 100% correlation between the results obtained by Mid Stream Pregnancy Test and the predicate device. It indicates that the Mid Stream Pregnancy test is substantially equivalent to the predicate device.
- The POL study and the evaluation carried out by different personnel with diverse educational background and work experience agreed 100% with the results expected, indicating that the testing results are highly repeatable. The precision of the test was found to be >99%.
- The consumer study carried out with 115 consumers demonstrated that the results obtained from consumers agreed 100% with that obtained from professionals. No discrepancy was found between the results obtained by Mid Stream Pregnancy Test and the predicate device. Over 99% of the consumers found the Mid Stream Test to be simple, fast, convenient, easy to understand and accurate.

Continued.....3

801 Montrose Avenue, S. Plainfield, NJ 07080 USA Tel: 908 754 4880 Fax: 908 754 5181
e mail : cs@inamco.com

- Based on the results of the consumer study, correlation study and the POL evaluations, we may conclude that Mid Stream Pregnancy Test is safe, as effective and performs as well as the legally marketed OTC device. It's intra and inter-assay precision is >99%. Therefore this device is suitable for use as an OTC Pregnancy Test.

801 Montrose Avenue, S. Plainfield, NJ 07080 USA Tel: 908 754 4880 Fax: 908 754 5181
e mail : cs@inamco.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 0 9 2003

Dr. D. M. Chouhan
President
Advanced Diagnostics, Inc.
801 Montrose Avenue
South Plainfield, NJ 07080

Re: k023037
Trade/Device Name: Mid Stream Pregnancy Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: LCX
Dated: February 5, 2003
Received: February 6, 2003

Dear Dr. Chouhan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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 Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510 (k) NUMBER (IF KNOWN) : K023037

DEVICE NAME : Mid Stream Pregnancy Test

INDICATIONS FOR USE :

The Test is a qualitative immunoassay intended for non professional / Over The Counter Use 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.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023037

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDE.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over the Counter Use ✓
(Per 21 CFR 801.109) (Optional Format 1-2-96)