1C023823

510(k) Summary

MAY 22 2003

As Required by 21 section 807.92 (c)

1-Submitter Name: Mansour Consulting LLC
2-Address: 1308 Morningside Park Dr
Alpharetta, GA 30022 USA
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5-Contact Person: Jay Mansour

6-Date summary prepared: November 1st, 2002

7-Device Trade or Proprietary Name: EASYCUP

8-Device Common or usual name: HCG EASYCUP PREGNANCY TEST

9-Device Classification Name: Radioimmunoassay, Human Chorionic Gonadotropin (HCG) test system

10-Substantial Equivalency is claimed against the following device:

- Surestep HCG Pregnancy test from APPLIED BIOTECH, INC 510k # K912801

11-Description of the Device:

hCG EASYCUP PREGNANCY TEST is a rapid one-step test for a visual qualitative detection of human Chorionic Gonadotropin (hCG) in urine. hCG (Human Chorionic Gonadotropin) is a glycoprotein hormone, secreted by the fertilized ovum shortly after fertilization. In normal pregnancies, hCG can be determined in urine as early as ten days following conception. hCG makes an excellent marker for the early detection of pregnancy, as it appears in urine soon after conception. Its concentration in urine increases rapidly during early gestational growth.

A nitrocellulose membrane is placed on a plastic backing. Two lines of antibodies are drawn on the membrane. One line, which is the test line, is coated with anti-α hCG. The other line, which serves as a control line, is pre-coated with anti-mouse IgG. A pad, soaked with anti-β hCG antibodies conjugated to colloidal gold particles, is placed on the membrane. Both sides of the membrane are covered with absorbing paper.

When the sample is positive (above 20 mIU/ml) the liquid moves through the pad of the anti-β antibodies. The antibodies bind the β subunit of the hormone. This complex labeled with gold moves through the membrane. When it arrives to the test line, the anti-α antibodies capture the complex by the α subunit of the hormone. The test line then becomes pink. When the rest of the gold conjugated antibodies reach the control line, the anti IgG antibodies capture, non specifically, the gold conjugated anti-β hCG antibodies, a second pink line is formed.

A negative sample (hCG below 20 mIU/ml) will not create a complex of gold labeled antibodies and hormone molecules, and no pink test line will form. A colored control line will always appear resulting from the viability of the antibodies.

12-Intended use of the device:

This device is indicated for use for the early detection of pregnancy to measure HCG, a placental hormone, in urine.

13-Safety and Effectiveness of the device:

This device is safe and effective as the other predicate device cited above. This is better expressed in the tabulated comparison (Paragraph 14 below)

14-Summary comparing technological characteristics with other predicate device:

Please find below a tabulated comparison supporting that this device is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency overview chart path is attached. Indeed, this device is **IDENTICAL** to the predicate device.

FDA file reference number	510k #K912801
Attachments inside notification submission file	Appendix 2 printouts from www.fda.gov: 510K and device classification
TECHNOLOGICAL CHARACTERISTICS	**Comparison result**
Indications for use	Identical
Target population	Identical
Design	Identical
Materials	Identical
Performance	Identical
Sterility	Identical (Not applicable)
Biocompatibility	Identical
Mechanical safety	Identical
Chemical safety	Identical
Anatomical sites	Identical
Human factors	Identical
Energy used and/or delivered	Identical
Compatibility with environment and other devices	Identical
Where used	Identical
Standards met	Identical
Electrical safety	Identical (not applicable)
Thermal safety	Identical (not applicable)
Radiation safety	Identical (not applicable)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2003

Zer Hitech Ltd.
Mr. Jay Mansour
FDA/ISO Regulatory Consultant for Medical Devices
Mansour Consulting LLC
1308 Morningside Park Drive
Alpharetta, GA 30022

Re: k023823
Trade/Device Name: EASYCUP
Regulation Number: 21 CFR 862.1155
Regulation Name: Human Chorionic Gonadotropin (HCG) Test System
Regulatory Class: Class II
Product Code: LCX, JHI
Dated: April 25, 2003
Received: May 7, 2003

Dear Mr. Mansour:

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). Other general information on your responsibilities under the Act may be obtained 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

510(k) Number (if known): **510k #K023823**

Device Name: **EASYCUP**

Indications for Use:

The Zer EasyCup is indicated for use for the early detection of pregnancy to qualitatively measure HCG, a placental hormone, in urine.

It is intended to be sold over the counter (OTC) and for professional use, and to be used directly by consumers at home, doctor's offices, laboratories, and hospitals.

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K023823

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

Concurence of CDRH, Office of Device Evaulation (ODE)

Prescription Use ( ) Over-the-Counter Use (X)

Per 21 CFR 801.109

(Optional Format 3-10-98)