K123050

510(K) SUMMARY

FEB 0 5 2013

1. Date: January 28, 2013

2. Submitter:

NanTong EGENS Biotechnology Co., Ltd.
Building 15, Building 12(west) , No. 1692 Xinghu Avenue,
Nantong Economy & Technology Development Zone,
226010 Nantong, P.R CHINA
Telephone:+85 513-85920700
Fax:0513-85328020

3. Name of contact person:

Joe Xia
LSI International Inc.
504 East Diamond Ave.,
Suite F Gaithersburg, MD 20878
Telephone: 301-250-0831
Fax: 301-916-6213
Email:jxia@lsi-consulting.org

4. Device Name:

EGENS One Step HCG Urine Pregnancy Test Kit (Strip)
EGENS One Step HCG Urine Pregnancy Test Kit (Cassette)
EGENS One Step HCG Urine Pregnancy Test Kit (Midstream I)
EGENS One Step HCG Urine Pregnancy Test Kit (Midstream II)

Classification: All are Class II medical devices with the following various product codes with Code of Federal Regulation references:

Product Code	CFR #
LCX	21 CFR, 862.1155
JHI	21 CFR, 862.1155

5. Predicate Devices:

1. K993317
   Acon Laboratories, Inc.
   ACON® One Step Pregnancy Test Device,

6. Intended Use:

EGENS One Step HCG Urine Pregnancy Test Kit (Strip) is a rapid chromatographic immunoassay for the qualitative detection of Human Chorionic Gonadotrophin (HCG) in urine samples to aid in the early detection of pregnancy by both professional and home users.

EGENS One Step HCG Urine Pregnancy Test Kit (Cassette) is a rapid chromatographic immunoassay for the qualitative detection of Human Chorionic Gonadotrophin (HCG) in urine samples to aid in the early detection of pregnancy by both professional and home users.

EGENS One Step HCG Urine Pregnancy Test Kit (Midstream I) is a rapid chromatographic immunoassay for the qualitative detection of Human Chorionic Gonadotrophin (HCG) in urine samples to aid in the early detection of pregnancy by home users.

EGENS One Step HCG Urine Pregnancy Test Kit (Midstream II) is a rapid chromatographic immunoassay for the qualitative detection of Human Chorionic Gonadotrophin (HCG) in urine samples to aid in the early detection of pregnancy by home users.

7. Device Description:

One Step HCG Urine Pregnancy Test measures the presence of the hormone Human Chorionic Gonadotrophin (HCG) in human urine for the early detection of pregnancy. During pregnancy, HCG is produced by the placenta shortly after the embryo attaches to the uterine lining. This test is capable of detecting pregnancy

the first day after a missed period. As pregnancy progresses, higher levels of HCG are present in urine at concentrations of 25mIU/ml (Milli-International Units) or greater. The concentration of HCG in non-pregnant women is normally 5.0mIU/ml. At the time of the last missed menstrual period, urine HCG levels are about 100mIU/ml with peak levels of 100,000 to 200,000mIU/ml. The test devices are in four different formats: Strip, Cassette, Midstream Ⅰ, and Midstream Ⅱ.

8. Substantial Equivalence Information

A summary comparison of the features of the One Step HCG Urine Pregnancy Test Kit (Strip), One Step HCG Urine Pregnancy Test Kit (Cassette), One Step HCG Urine Pregnancy Test Kit (Midstream I), One Step HCG Urine Pregnancy Test Kit (Midstream II), and the predicate devices is shown in the following Tables.

Features Comparison of One Step HCG Urine Pregnancy Test Kit (Strip, Cassette, Midstream I, Midstream II) and the Predicate Devices

Item	Device	Predicate – K993317
Indication(s) for Use	For the qualitative determination of hCG in urine.	Same
User	Prescription and over the counter	Prescription
Format	Strip, cassette	cassette
Type of Test	Colloidal Gold Immunoassay	Same
Specimen Type	Human Urine	Same
Cut Off Values	25 mIU/mL	Same
Traceability	WHO International Standard 3rd Edition	Same

Item	Device	Predicate – K993317
Indication(s) for Use	For the qualitative determination of hCG in urine.	Same
User	over the counter	Prescription
Format	midstream	cassette
Type of Test	Colloidal Gold Immunoassay	Same
Specimen Type	Human Urine	Same
Cut Off Values	25 mIU/mL	Same
Traceability	WHO International Standard 3rd Edition	Same

EGENS one step HCG urine pregnancy test kits have similar technological characteristics and performances to the predicate.

9. Standard/Guidance Document Reference

- ISO 14971:2007, Medical Devices-Application of Risk Management to Medical Devices

10. Test Principle

One Step HCG Urine Pregnancy Test measures the presence of the hormone Human Chorionic Gonadotrophin (HCG) in human urine for the early detection of pregnancy. During pregnancy, HCG is produced by the placenta shortly after the embryo attaches to the uterine lining. This test is capable of detecting pregnancy the first day after a missed period. As pregnancy progresses, higher levels of HCG are present in urine at concentrations of 25mIU/ml (Milli-International Units) or greater. The concentration of HCG in non-pregnant women is normally 5.0mIU/ml. At the time of the last missed menstrual period, urine HCG levels are about 100mIU/ml with peak levels of 100,000 to 200,000mIU/ml.

The HCG assay is a rapid one-step test based on immunochromatographic technology. This device is composed of glass fiber strips of the monoclonal antibody against HCG, anti-mouse IgG, solid cellulose nitrate membrane, and the bonders of absorptive colloidal gold - monoclonal antibody against HCG. It adopts the principles of the double antibody sandwich method and imunochromatography technology to test for the presence of HCG in urine.

11. Summary

The information provided in this pre-market notification demonstrates that EGENS One Step HCG Urine Pregnancy Test Kit (Strip), EGENS One Step HCG Urine Pregnancy Test Kit (Cassette), EGENS One Step HCG Urine Pregnancy Test Kit (Midstream I) and EGENS One Step HCG Urine Pregnancy Test Kit (Midstream II) are substantially equivalent to ACON® One Step Pregnancy Test Device. Substantial equivalence was demonstrated through comparison of intended use and physical properties to the commercially available and analytical predicate devices. The information supports substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

EGENS Biotechnology
c/o Joe Xia
Regulatory Affairs
12828 Doe Lane
Gaithersburg, Maryland 20878

FEB 0 5 2013

Re: k123050
Trade/Device Name: EGENS One Step HCG Urine Pregnancy Test Kit (Strip)
EGENS One Step HCG Urine Pregnancy Test Kit (Cassette)
EGENS One Step HCG Urine Pregnancy Test Kit (Midstream I)
EGENS One Step HCG Urine Pregnancy Test Kit (Midstream II)

Regulation Number: 21 CFR 862.1155
Regulation Name: Human Chorionic Gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: LCX, JHI
Dated: January 28, 2013
Received: January 30, 2013

Dear Mr. Xia,

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 additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k123050

Device Name: EGENS One Step HCG Urine Pregnancy Test Kit (Strip)
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Indications for Use:

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EGENS One Step HCG Urine Pregnancy Test Kit (Midstream I) is a rapid chromatographic immunoassay for the qualitative detection of human Chorionic Gonadotropin (hCG) in urine samples to aid in the early detection of pregnancy by home users.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

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Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

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Indications for Use:

EGENS One Step HCG Urine Pregnancy Test Kit (Midstream II) is a rapid chromatographic immunoassay for the qualitative detection of human Chorionic Gonadotropin (hCG) in urine samples to aid in the early detection of pregnancy by home users.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ___X___ (21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-Iyles -S
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Division Sign-Off
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