K072500

SECTION 4 SUMMARY

Submitter's name: Guangzhou Wondfo Biotech Co., Ltd.
Address: South China University of Technology
Guangzhou, P.R. China 510641
Phone: 00-86-20-871-1274-8668

APR 21 2009

Name of contact person:
Howard Mann
SHERBO ASSOCIATES
8903 Spruce Mill Drive
Yardley, PA 19067
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Date the summary was prepared: August 28, 2007

Name of the device: One Step HCG Urine/Serum Test
Trade or proprietary name: One Step HCG Urine/Serum Test
Common or usual name: HCG Urine/Serum Test

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

Product Code	CFR #
DHA	862.1155

The legally marketed device to which we are claiming equivalence [807.92(a)(3)]:
Acon Laboratories, Inc. HCG One Step Urine/Serum Pregnancy Test, K980736.

Description of the device:

Assay Principle: Human Chorionic Gonadotropin (HCG) is one of the glycoproteins secreted by the placenta. It contains α-and β-subunits. The α-subunit of HCG shows cross-reactions with LH, TSH and FSH, because of similarities in the amino acid sequences. However, the β-subunit of HCG is specific, and shows the lowest cross reactions in assays. The antibodies, which were used before in HCG detection, were directed against the whole HCG molecule, and therefore regularly presented cross reactions with LH and TSH. Wondfo One Step HCG Urine/Serum Test is aimed to be a HCG specific test by using a monoclonal antibody against highly purified β-HCG. Immunochromatograph assay for hCG using a lateral flow, one step system for the qualitative detection of hCG in human urine/serum. Each assay uses a monoclonal antibody-dye congugate from mouse against β-HCG with gold chloride and fixed α-HCG antibody conjugate and anti-mouse IgG polyclonal antibody in membrane.

Intended use of the device:

The One Step HCG Urine/Serum Test is used for the qualitative determination of HCG which appears in urine or serum for early detection of pregnancy. They are intended for professional use。

Summary of the technological characteristics of our device compared to the predicate device:

The Wondfo Biotech Co., Ltd. One Step HCG Urine/Serum Test have similar technological characteristics and performance to the predicate and are equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Guangzhou Wondfo Biotech Co., Ltd.
c/o Mr. Howard Mann
Official Correspondent
Sherbo Associates
8903 Spruce Mill Drive
Yardley, PA 19067

APR 21 2009

Re: k072500
Trade/Device Name: Wondfo One Step HCG Urine/Serum Test
Regulation Number: 21 CFR §862.1155
Regulation Name: Human Chorionic Gonadotropin (HCG) Test System.
Regulatory Class: Class II
Product Code: DHA
Dated: January 15, 2009
Received: January 21, 2009

Dear Mr. Mann:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): k072500

Device Name: Wondfo One Step HCG Urine/Serum Test

Indication For Use:

Wondfo One Step HCG Urine/Serum Test is an *in-vitro* diagnostic test for qualitative determination of human chorionic gonadotropin (HCG) in human serum or urine to aid in the early detection of pregnancy. It is intended for professional use only (Clinical Laboratory Use).

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K072500