Exhibit 1 510(k) Summary

1 510(k) Summary

Date of Summary Preparation: May 17, 2004

1.2 Submitter:

Mr. Jason Zhou
Guangzhou Wondfo Biotech Co., Ltd.
WONDFO Scientech Park
South China University of Technology
Guangzhou, Guangdong, PRC, 510641
E-mail: jason@wondfo.com.cn

1.3 Trade Name: One Step HCG Urine Pregnancy Test

1.4 Classification Name, Product Code, Class, Classification Reference:

Classification Name	Common Name	Product Code	Class	21CFR §
Kit, test, pregnancy, hcg, over the counter	Pregnancy Test	LCX	II	862.1155
Kit, test, pregnancy, hcg, professional and laboratory use	Pregnancy Test	JHI	II	862.1155

1.5 Standards/Special Controls:

None

1.6 Indications for Use:

The Guangzhou Wondfo Biotech Co., Ltd. One Step HCG Urine Pregnancy Test is intended for non-professional, over-the-counter use and for professional use for the qualitative identification of the elevated levels of human Chorionic Gonadotropin (hCG) in urine to aid in the determination of pregnancy.

The One Step HCG Urine Pregnancy Test is intended for use by professional healthcare personnel trained in its use and for Over-the-Counter use.

1.7 Device Description:

The device consists of a single test strip with one end designated for dipping, and control and test regions in the middle. At one end of the strip are arrows indicating which end of the strip is dipped into the urine and a MAX line indicating that the strip should not be dipped below this line.

The One Step HCG Urine Pregnancy Test device is similar in design, materials and intended use to other 510(k) cleared devices, which are in commercial distribution.

1.8 Substantially Equivalent Commercially Available Devices:

The One Step HCG Urine Pregnancy Test device is substantially equivalent to the predicate device described herein with respect to indications for use, device design, materials, and method of manufacture:

Unipath, Ltd, E.P.T. Pregnancy Test – K033658
Biotech Atlantic, Inc., Unimark Home Pregnancy Test Device – K032992
Acon Laboratories, Inc, Acon Quick-Check II Home Pregnancy Test Strip – K033041
Standard Diagnostics, Inc., Good Morning Test – K031798

The predicate devices are commercially available and marketed Class II devices indicated for use for non-professional, over-the-counter use and for professional use for the qualitative identification of the elevated levels of human Chorionic Gonadotropin (hCG) in urine to aid in the determination of pregnancy.

1.9 Substantial Equivalence Comparison:

See Section 5: Comparison Chart.

1.10 Indications and Contraindications:

Relative indications and contraindications for the Guangzhou Wondfo Biotech Co., Ltd. One Step HCG Urine Pregnancy Test and commercially available devices for similar intended uses are the same.

1.11 Conclusion:

In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this pre-market notification, Guangzhou Wondfo Biotech Co., Ltd concludes that the new device, One Step HCG Urine Pregnancy Test, is safe, effective and substantially equivalent to the predicate device as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 7 2005

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

Re: k043443
Trade/Device Name: One Step HCG Urine Pregnancy Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: LCX, JHI
Dated: February 26, 2005
Received: February 28, 2005

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); 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 (240)276-0484. 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/industry/support/index.html

Sincerely yours,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

EXHIBIT B Indications for Use Statement

Indications for Use

510(k) Number (if known):

Device Name: One Step HCG Urine Pregnancy Test

Indications for Use:

The Guangzhou Wondfo Biotech Co., Ltd. One Step HCG Urine Pregnancy Test is intended for non-professional, over-the-counter use and for professional and laboratory use for the qualitative identification of the elevated levels of human Chorionic Gonadotropin (hCG) in urine to aid in the determination of pregnancy.

The One Step HCG Urine Pregnancy Test is intended for use by professional healthcare personnel trained in its use and for Over-the-Counter use.

Prescription Use ✓ **(Part 21 CFR 801 Subpart D)** **AND/OR** **Over-The-Counter Use** ✓ **(21 CFR 807 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K043443