K050094

APPENDIX A

APR 20 2006

510 K Summary

Submitter's Name: Lady-Comp USA

Address: 410 East Terrace Heights
Jeffersonville, Indianna, USA
47130

Telephone: 502 905 2601
1 866 202 2193

Fax: 812 288 8407

Contact Person: Michael Cartain

Date of Summary: January 6, 2005

Trade Name: Lady-Comp® USA

Common name: Computerized Basal Body Temperature Thermometer

Classification: Device, Fertility Diagnostic, Proceptive
Product Code: LHD
Unclassified Device

Predicate Device: Petit Sophia, Computerized Basal Body Thermometer, Model No. BT-14E

Device Description: Lady-Comp® USA is a computerized basal body temperature thermometer with the following functions:

1) Alarm clock function for measuring temperature at a consistent time.

2) Measuring accuracy within +/- 0.05°C (0.09°F).

3) Displaying the measured temperature.

4) Generating the measurement completion signal.

5) Memory Capacity of data for 180 days.

6) Transferring the stored data to an external instrument.

Intended Use: Lady-Comp®USA is intended for measuring and recording basal body temperature (BBT) as an aid in ovulation prediction to facilitate conception (not to be used for contraception).

Technological Characteristics: Lady-Comp®USA has the same general design and performance characteristics as the predicate device, Petit Sophia, which is manufactured by Nishitomo Co., Ltd. The main differences include the physical size and shape, display and sensor. Lady-Comp® USA has the same intended use, general design and function, and similar materials and components as the predicate device. Thus, Lady-Comp®USA is considered to be substantially equivalent to the predicate device, Petit Sophia.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

APR 20 2006

Mr. Michael Cartain
Branch Manager
Lady-Comp USA
410 East Terrace Heights
JEFFERSONVILLE IN 47130

Re: K050094
Trade/Device Name: LadyComp® USA
Regulation Number: None
Regulatory Class: Unclassified
Product Code: LHD
Dated: March 27, 2006
Received: March 31, 2006

Dear Mr. Cartain:

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 (Premarket Approval), it may be subject to such 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); 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.

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 Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050094
Device Name: Lady-Comp®
USA
Indications for Use:

Lady-Comp® USA is intended for measuring and recording basal body temperature (BBT) as an aid in ovulation prediction to facilitate conception (not to be used for contraception).

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use X (21 CFR 801 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)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050094