DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 19 2005

Ms. Eve Schwartz
VP of Operations
Salimetrics, LLC
101 Innovation Boulevard
Suite 302
State College, PA 16803

Re: k051012
Trade/Device Name: Salimetrics Progesterone Standard Calibrator and Control
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT, JJY
Dated: April 13, 2005
Received: April 25, 2005

Dear Ms. Schwartz:

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,

Carol C. Benson

Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

## Indications for Use

**510 (k) Number: K051012**

**Device Name:** Progesterone Standard Calibrator, one (1)mL of progesterone in a saliva-like matrix at a concentration of 2430 pg/mL with a non-mercury preservative.

Progesterone High Control (1000 pg/mL) and Progesterone Low Control (50.6 pg/mL), 0.5 mL vials in a saliva-like matrix with a non-mercury preservative.

**Indications for Use:**

The salivary progesterone calibrator is a device intended for medical purposes to use in the Salimetrics competitive enzyme immunoassay to establish points of reference that are used to determine values in the measurement of free progesterone in saliva.

The salivary progesterone controls are devices intended for use in monitoring the performance of the salivary immnuoassay of free progesterone in saliva.

Prescription Use: __X__ and/or Over-the-Counter Use (OTC): _____

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## Concurrence of CDRH, Office of *In Vitro* Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K051012