K101460

510(k) Summary for LOCI 8 Calibrator

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____

1. **Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:**

Manufacturer: Siemens Healthcare Diagnostics, Inc.

500 GBC Drive

Newark, DE 19714

JUL - 9 2010

Contact Information: Siemens Healthcare Diagnostics, Inc.

500 GBC Drive

Newark, DE 19714

Attn: A. Kathleen Ennis

Tel: 302-631-9352

Fax: 302-631-6299

Preparation date: April 26, 2010

2. **Device Name:** LOCI 8 Calibrator

Classification: Class II

Product Code: JIX;

Panel: Clinical Chemistry (75)

3. **Identification of the Legally Marketed Device:**
Siemens Calibrator B, k962041 (FSH, LH, Prolactin)
Roche Estradiol II CalSet II , k992981 (Estradiol)

4. **Device Descriptions:**

LOCI 8 CAL is a multi-analyte, liquid, frozen bovine serum albumin based product containing human follicle stimulating hormone, human luteinizing hormone, recombinant human prolactin, estradiol, buffers and preservatives.

5. **Device Intended Uses:**

Dimension LOCI 8 Calibrator

The LOCI 8 is an *in vitro* diagnostic product for the calibration of the Prolactin (PRL), Luteinizing Hormone (LH), Follicle Stimulating Hormone (FSH) and Estradiol (E2) methods on the Dimension Vista® system.

6. **Medical device to which equivalence is claimed and comparison information:**
The LOCI 8 CAL is substantially equivalent to Siemens Calibrator B and Roche Estradiol CalSet II. Like the predicates, LOCI 8 is an *in vitro* diagnostic product intended to be used for the calibration of hormone assays on automated immunoassay analyzers.

7. Comparative Features Table

Feature	Predicate Device Siemens Calibrator B (k962041)	New Device Dimension Vista® LOCI 8 CAL
Similarities		
Intended Use:	Calibrator B is for *in vitro* diagnostic use in the calibration of the following assays FSH, LH and Prolactin.	LOCI 8 CAL is an *in vitro* diagnostic product for calibration of the follicle stimulating hormone (FSH), luteinizing hormone (LH) and prolactin (PRL).
Constituents:	FSH, LH, Prolactin.	FSH, LH, prolactin,
Traceability of constituents:	FSH LH Prolactin	FSH - WHO 1st IS for FSH 92/510 LH - WHO 2nd IS for LH 80/552 Prolactin - WHO 3rd IS for PRL 84/500
Differences		
Intended Use	Calibrator B is for use on the ADVIA Centaur® or ACS:180 systems Calibrator B is also used for the calibration of digoxin, Total IGE, Total hCG and TSH	LOCI 8 CAL is for use on the Dimension Vista® System. LOCI 8 Calibrator is also used for estradiol (E2).
Form	Lyophilized equine serum	frozen liquid, bovine serum albumin
Traceability of Constituents		Estradiol - Isotope Dilution gas chromatography mass spectroscopy reference measurement procedure
Levels:	2	5
Stability and	Calibrator B is stored at 2 – 8	LOCI 8 CAL is stored at - 25 to -15 °

storage	° C. Calibrator B is stable, reconstituted for 28 days @ 2 – 8 ° C.	C. LOCI 8 CAL is stable, thawed and unopened for 8 days @ 2 – 8 ° C.

Feature	Predicate Device Roche – Estradiol II CalSet II (k992681)	New Device Dimension Vista® LOCI 8 CAL
Similarities		
Intended Use:	Elecsys Estradiol II CalSet II is an *in vitro* diagnostic product used for calibrating a quantitative estradiol assay.	LOCI 8 CAL is an *in vitro* diagnostic product for calibration of a quantitative estradiol assay.
Constituents:	Estradiol	Estradiol
Traceability of constituents:	The Elecsys Estradiol II assay has been standardized using ID-GC/MS (isotope dilution-gas chromatography).	The E2 assay on the Dimension Vista® has been standardized using ID-GC/MS (isotope dilution-gas chromatography).
Differences		
Intended Use	The Elecsys Estradiol II CalSet II is for use on the Elecsys and **cobas e** immunoassay analyzers. The Elecsys Estradiol II CalSet II is for use only in the calibration of Estradiol II.	LOCI 8 CAL is for use on the Dimension Vista® System. LOCI 8 Calibrator is also used for the calibration of follicle stimulating hormone (FSH), luteinizing hormone (LH) and prolactin (PRL).
Form	Lyophilized human serum	frozen liquid, bovine serum albumin
Levels:	2	5
Stability and storage	Elecsys Estradiol II CalSet II is stored at 2 – 8 ° C. Elecsys Estradiol II CalSet II is stable, reconstituted three months when stored at – 20 ° C if frozen only once.	LOCI 8 CAL is stored at - 25 to -15 ° C. LOCI 8 CAL is stable, thawed and unopened for 8 days @ 2 – 8 ° C

8. Conclusion

LOCI 8 CAL, is substantially equivalent in intended use to the legally marketed devices, Siemens Calibrator B (k962041) and Roche – Estradiol II CalSet II (k992981) based on the information described above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Siemens Healthcare Diagnostics, Inc.
c/o Ms. Anna Marie Ennis
Senior Regulatory Affairs &
Compliance Specialist
500 GBC Drive, PO Box 6101
Newark, Delaware 19714-61015

JUL 09 2010

Re: k101460
Trade Name: Loci 8 Calibrator, Model KC 646
Regulation Number: 21 CFR §862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Codes: JIX
Dated: May 25, 2010
Received: May 26, 2010

Dear Ms. Ennis:

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).

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 (301) 796-5450. 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 (301) 796-5760. 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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
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 Form

510(k) Number (if known): K101460

Device Name: LOCI 8 CAL

Indications for Use: LOCI 8 CAL is an in vitro diagnostic product for the calibration of follicle stimulating hormone (FSH), luteinizing hormone (LH), prolactin (PRL) and estradiol (E2) methods on the Dimension Vista® Systems.

Prescription Use XX (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

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

Carol Benson

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

510(k) K101460