DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 17, 2016

SIEMENS HEALTHCARE DIAGNOSTICS
SUSAN FERRIN
REGULATORY AFFAIRS CLINICAL SPECIALIST
333 CONEY STREET
E. WALPOLE, MA 02032

Re: K162538
Trade/Device Name: ADVIA Centaur Insulin (IRI) Master Curve Material (MCM)
ADVIA Centaur (IRI) Calibrator
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: II
Product Code: JIT, JJX
Dated: October 17th, 2016
Received: October 18th, 2016

Dear Ms. Ferrin:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k162538

Device Name
ADVIA Centaur® Insulin (IRI) M aster Curve Material (MCM)
ADVIA Centaur® Insulin (IRI) Calibrator

Indications for Use *(Describe)*
The ADVIA Centaur® Insulin (IRI) Master Curve Material (MCM) is for in vitro diagnostic use in the verification of calibration and reportable range of the ADVIA Centaur® Insuin assay.

The ADVIA Centaur® Insulin (IRI) Calibrator is for in vitro diagnostic use in calibrating the ADVIA Centaur® systems Insulin assays.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

A summary of information in accordance with 21 CFR 807.92 is provided below.

The assigned 510(k) Number K162538

Applicant Information **Siemens Healthcare Diagnostics Inc.**
Mailing Address: 333 Coney Street
East Walpole, MA 02032

Contact Person: Susan Ferrin

Phone Number: 508-660-4487
Fax Number: 508-660-4591
E-mail Address: susan.ferrin@siemens.com

Date Prepared: November 16, 2016

Device Information **Trade/Proprietary Name**	**ADVIA Centaur® Insulin (IRI) Master Curve Material (MCM)**	**ADVIA Centaur® Insulin (IRI) Calibrator**
Common/Usual Name	Assay verification material	Calibrator/normalizer
Regulation Section	21 CFR 862.1660	21 CFR 862.1150
Classification	Class I Reserved	Class II
Products Code	JJX – Single (Specified) Analyte Controls (Assayed and Unassayed)	JIT – Calibrator, Secondary
Panel	Clinical Chemistry (75)	Clinical Chemistry (75)
Predicate	ADVIA Centaur® Insulin (IRI) Master Curve Material (MCM)	ADVIA Centaur® Insulin (IRI) Calibrator
510(k) No.	K142864	K021535

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Device Description:	ADVIA Centaur® Insulin (IRI) Master Curve Material is a set of ten vials of material containing various levels of insulin in buffered saline with casein, potassium thiocyanate (3.89%), sodium azide (<0.1%), and preservatives. Each set contains ten levels (MCM1–10); ready-to-use 1.0 mL per level. MCM1 contains no analyte. The IRI MCMs assigned values are lot-specific of target values: 0.0, 2.5, 4.5, 10.0, 20.0, 39.0, 79.0, 158, 225, and 330 mU/L.	ADVIA Centaur® Insulin (IRI) Calibrator is a set of four vials (two vials of low calibrator and two vials of high calibrator) comprised of buffered saline, with casein, potassium thiocyanate, sodium azide and preservative. Only the high calibrator contains insulin.
Intended Use and Indications for Use	The ADVIA Centaur® Insulin (IRI) Master Curve Material is for *in vitro* diagnostic use in the verification of calibration and reportable range of the ADVIA Centaur® Insulin assay.	The ADVIA Centaur® Insulin (IRI) Calibrator is for *in vitro* diagnostic use in calibrating the ADVIA Centaur® systems Insulin assays.
Special Conditions for Use Statement(s)	For prescription use only	None
Instrument Requirements:	ADVIA Centaur® Systems A description of the ADVIA Centaur® system is documented in K971418. Subsequent modifications to the instrument have been reviewed and cleared in K032525 and K041133.	ADVIA Centaur® Systems A description of the ADVIA Centaur® system is documented in K971418. Subsequent modifications to the instrument have been reviewed and cleared in K032525 and K041133.
Comparison of Technological Characteristics:	Summarized in Table 1 below.	Summarized in Table 2 below.

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Table 1: ADVIA Centaur® Insulin (IRI) Master Curve Material

Characteristic	Candidate Device - ADVIA Centaur® Insulin Master Curve Material (MCM)	Cleared Device - ADVIA Centaur® Insulin Master Curve Material (MCM)
Intended Use	Same	The ADVIA Centaur® Insulin (IRI) Master Curve Material is for *in vitro* diagnostic use in the verification of calibration and reportable range of the ADVIA Centaur Insulin assay.
Instrument	Same	ADVIA Centaur Systems
Form	Same	Liquid
Matrix	Same	Buffered saline with casein, postassium thiocyanate, sodium azide and preservatives
Ingredient	Human Insulin (porcine sourced)	Human Insulin (human sourced)
Number of Levels	Same	10
Target Concentrations	Same	0.0, 2.5, 4.5, 10.0, 20.0, 39.0, 79.0, 158, 225, 330 mU/L
Fill Volume	Same	1.0 mL
Shelf Life/Stability	Same	12 months at 2-8 degrees C
On board Stability	Same	8 hours on board

Table 2: ADVIA Centaur® Insulin (IRI) Calibrator

Characteristic	Candidate Device ADVIA Centaur® Insulin Calibrator	Predicate Device ADVIA Centaur® Insulin Calibrator
Intended Use	Same	The ADVIA Centaur® Insulin (IRI) Calibrator is for *in vitro* diagnostic use in calibrating the ADVIA Centaur® systems Insulin assays.
Instrument	Same	ADVIA Centaur Systems
Form	Same	Liquid
Matrix	Same	Buffered saline with casein, potassium thiocyanate, sodium azide and preservatives
Ingredient	Human Insulin (porcine sourced)	Human Insulin (human sourced)
Number of Levels	Same	2
Target Concentrations	Same	Low: <0.5 mU/L 135 – 165 mU/L
Fill Volume	Same	1.0 mL
Shelf Life/Stability	Same	18 months at 2-8 degrees C
On board Stability	Same	8 hours

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Summary of Design Control Activities

The procedure for risk management activities is based on ISO 14971 (2007), Medical Devices – Application of Risk Management to Medical Devices and the risk analysis method used to assess the impact of the device modification was a Failure Modes and Effects Analysis. The following performance characteristics of the devices were considered for potential hazards: Shelf Life (closed vial) and Shelf Life (onboard). Verification testing was conducted and results show that the modified devices meet pre-determined acceptance criteria. Additionally, a method comparison study demonstrates that human clinical sample results are equivalent with both calibrators (modified and unmodified) using different antigen sources (human and porcine). The modification does not negatively impact the performance of the devices or the safety and effectiveness of the devices.

Conclusion

The modified ADVIA Centaur® Insulin (IRI) Master Curve Material (MCM) and ADVIA Centaur® Insulin (IRI) Calibrator devices are substantially equivalent to the currently marketed ADVIA Centaur® Insulin (IRI) Master Curve Material (MCM) and ADVIA Centaur® Insulin (IRI) Calibrator. Based on the testing completed and the comparisons with predicate device, the ADVIA Centaur® Insulin (IRI) Master Curve Material (MCM) and ADVIA Centaur® Insulin (IRI) Calibrator devices do not raise any new questions on safety and effectiveness and the results support a determination of substantial equivalence.