MAR 18 2011

510(k) Summary of Safety and Effectiveness for the

Emit® II Plus 6-Acetylmorphine Assay

Emit® II Plus 6-AM / Ecstasy Calibrators / Controls Levels 1 - 4

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR807.92.

A. 510(k) Number: k102779

B. Date of Preparation: March 1, 2011

C. Proprietary and Established Names

Emit® II Plus 6-Acetylmorphine Assay

Emit® II Plus 6-AM / Ecstasy Calibrator / Control Level 1
Emit® II Plus 6-AM / Ecstasy Calibrator / Control Level 2
Emit® II Plus 6-AM / Ecstasy Calibrator / Control Level 3
Emit® II Plus 6-AM / Ecstasy Calibrator / Control Level 4

D. Applicant:

Siemens Healthcare Diagnostics Inc.

P.O. Box 6101, Newark, DE 19714-6101

Janet Fose, Regulatory Technical Specialist, Regulatory Affairs

Office: (302) 631-8826 Fax: (302) 631-6299

E. Regulatory Information:

Emit® II Plus 6-Acetylmorphine Assay:

1. Regulation section: 21 CFR § 862.3650 - Opiate test system
2. Classification: Class II
3. Product Code: DJG – Enzyme Immunoassay, Opiates
4. Panel: Clinical Toxicology (91)

Emit® II Plus 6-AM / Ecstasy Calibrators / Controls Levels 1 – 4:

Calibrator
1. Regulation section: 21 CFR § 862.3200 – Clinical toxicology calibrator
2. Classification: Class II
3. Product Code: DKB – Calibrators, Drug Mixture
4. Panel: Clinical Toxicology (91)

Control
1. Regulation section: 21 CFR § 862.3280 – Clinical toxicology control material
2. Classification: Class I, reserved
3. Product Code: DIF – Drug Mixture Control Materials
4. Panel: Clinical Toxicology (91)

F. Predicate Device(s):

Emit® II Plus 6-Acetylmorphine Assay:

The Emit® II Plus 6-Acetylmorphine Assay is substantially equivalent to the Microgenics Corporation CEDIA® DAU 6-Acetylmorphine Assay cleared under k001178. Both are designed for use on a number of chemistry analyzers.

Emit® II Plus 6-AM / Ecstasy Calibrators / Controls Levels 1 – 4:

Calibrator
The Emit® II Plus 6-AM / Ecstasy Calibrators / Controls are substantially equivalent to the Emit® II Plus Ecstasy Calibrators / Controls cleared under k043028.

Control
The Emit® II Plus 6-AM / Ecstasy Calibrators / Controls are substantially equivalent to the Emit® II Plus Ecstasy Calibrators / Controls cleared under k043028. The Emit® Calibrator / Control Level 0, which was cleared under k993755 will also be used with the Emit® II Plus 6- Acetylmorphine Assay. There was no change to the Calibrator Level 0.

G. Device Description(s):

Emit® II Plus 6-Acetylmorphine Assay:

The Emit® II Plus 6-Acetylmorphine Assay is a homogenous enzyme immunoassay with a 10 ng/mL cutoff. The assay, used for the detection of 6-acetylmorphine (a heroin metabolite) in human urine, utilizes a two-reagent system. The Antibody/Substrate Reagent 1 is a liquid ready-to-use product comprised of mouse monoclonal antibodies to 6-acetylmorphine (6-AM), glucose-6-phosphate (G6P), and nicotinamide adenine dinucleotide (NAD) in a diluent containing bovine serum albumin (BSA), preservatives and stabilizers. The Enzyme Reagent 2 is a lyophilized product containing 6-AM labeled bacterial recombinant glucose-6-phosphate dehydrogenase (rG6PDH) in a diluent containing bovine serum albumin (BSA), Hepes buffer, preservatives and stabilizers. Reagent 2 is reconstituted with either deionized or distilled water.

The assay kit consists of Reagent 1 and Reagent 2 in plastic containers (Reagent 2 is provided in a plastic bag with desiccant) and is available in two sizes. Emit® II Plus Assays are designed for use with a number of chemistry analyzers.

Emit® II Plus 6-AM / Ecstasy Calibrators / Controls Levels 1 – 4:

The Emit® II Plus 6-AM / Ecstasy Calibrators / Controls are in-vitro diagnostic products used in the calibration of the Emit® II Plus 6-Acetylmorphine Assay and the Emit® II Plus Ecstasy Assay. These materials may also be used as quality controls based on the specific 6-Acetylmorphine Assay or Ecstasy Assay cutoffs.

The calibrator / control products have the same formulation as the existing Emit® II Plus Ecstasy Calibrators / Controls; cleared under k043028. The matrix is pooled, drug-free, human urine based product containing 6- acetylmorphine (6-AM), methylenedioxymethamphetamine (MDMA) and preservatives. The four levels of product are packaged separately in 15 mL plastic vials with a 10 mL fill per vial.

The multi-analyte Calibrators / Controls Levels 1 through 4 contain 6-AM and MDMA at the following concentrations:

Calibrator / Control	Targeted 6-AM Concentration (ng/mL)	Targeted MDMA Concentration (ng/mL)
Level 1	5	150
Level 2	10	300
Level 3	15	500
Level 4	20	1000

The Emit® Calibrator / Control Level 0, which contains no drug and was cleared under k993755 will also be used with the Emit® II Plus 6-Acetylmorphine Assay. There was no change to the Calibrator Level 0 product.

H. Intended Use:

Emit® II Plus 6-Acetylmorphine Assay:

The Emit® II Plus 6-Acetylmorphine Assay is a homogeneous enzyme immunoassay with 10 ng/mL cutoff. The assay is intended for use in laboratories for the qualitative and/or semiquantitative analyses of 6-acetylmorphine (6-AM), a heroin metabolite, in human urine. Emit® II Plus assays are designed for use with a number of chemistry analyzers.

Semiquantitative test results may be used to assess assay performance as part of a quality control program and to estimate a dilution of the specimen for confirmation by GC/MS.

The Emit® II Plus 6-Acetylmorphine Assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectroscopy (GC/MS) is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug-of-abuse test result, particularly when preliminary positive results are used.

Emit® II Plus 6-AM/Ecstasy Calibrators/Controls:

When used as Calibrators, the materials are for the calibration of the Emit® II Plus 6-Acetylmorphine and Emit® II Plus Ecstasy Assays.

When used as Controls, the materials may be used as quality control materials based on the specific Emit® II Plus 6-Acetylmorphine and Emit® II Plus Ecstasy Assay cutoffs.

I. Substantial Equivalence Information:

The Emit® II Plus 6-Acetylmorphine Assay was compared to the Microgenics predicate device CEDIA® DAU 6-Acetylmorphine Assay (k001178). The Emit® II Plus 6-AM / Ecstasy Calibrators / Controls were compared to Siemens Healthcare Diagnostics Inc. Emit® II Plus Ecstasy Calibrators / Controls Levels 1 – 4 (k043028). A comparison of the important similarities and differences between the devices and the predicates is provided in the following tables:

Comparison of Assay Features

Feature	**Proposed Device** **Emit® II Plus 6-Acetylmorphine Assay**	**Predicate** **CEDIA® DAU 6-Acetylmorphine Assay (k001178)**
Intended Use	The Emit® II Plus 6-Acetylmorphine Assay is a homogeneous enzyme immunoassay with 10 ng/mL cutoff. The assay is intended for use in laboratories for the qualitative and/or semiquantitative analyses of 6-acetylmorphine (6-AM), a heroin metabolite, in human urine. Emit® II Plus assays are designed for use with a number of chemistry analyzers. Semiquantitative test results may be used to assess assay performance as part of a quality control program and to estimate a dilution of the specimen for confirmation by GC/MS. The Emit® II Plus 6-Acetylmorphine Assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectroscopy (GC/MS) is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug-of-abuse test result, particularly when preliminary positive results are used.	The CEDIA® Heroin Metabolite (6-Acetylmorphine, or 6-AM) Assay is an in vitro diagnostic medical device intended for the qualitative and semiquantitative analysis of heroin metabolite (6-AM) in human urine.* The assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used to obtain a confirmed analytical result. Gas chromatography / mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are observed.* *From the predicate device IFU

Feature	Proposed Device Emit® II Plus 6-Acetylmorphine Assay	Predicate CEDIA® DAU 6-Acetylmorphine Assay (k001178)
Assay Methodology	Homogeneous enzyme immunoassay using EMIT® technology	Homogeneous enzyme immunoassay using CEDIA® technology
Antibody	Mouse monoclonal antibodies to 6-AM	Monoclonal antibodies to 6-AM
Reference Methodology	GC / MS	GC / MS
Cutoff	10 ng/mL	10 ng/mL
Sample Type	Human urine	Human urine
Reagents: Form	R1: Liquid – Ready to Use R2: Lyophilized (Reconstitution required)	R1 & R2: Lyophilized (Reconstitution required)
Stability (Reconstituted)	R1: Until Exp. on vial R2: 30 days	R1 & R2: 60 days
Instrument	Chemistry analyzers capable of maintaining constant reaction temperature, pipetting specimens/reagents and measuring enzyme rates at 340 nm, timing reaction accurately and mixing reagent thoroughly	Clinical chemistry analyzers capable of maintaining constant temperature, pipetting samples, mixing reagents, measuring enzymatic rates at 570 nm and timing the reaction accurately

Comparison of Calibrator Features

Feature	Proposed Device Emit® II Plus 6-AM / Ecstasy Calibrators / Controls	Predicate Emit® II Plus Ecstasy Calibrators / Controls (k043028)
Indications for Use	Calibrators are used in the calibration of the Emit® II Plus 6-Acetylmorphine and Emit® II Plus Ecstasy Assays.	The Emit® II Plus Ecstasy Calibrators/ Controls are used in the calibration of the Emit® II Plus Ecstasy Assay. These standards may also be used as quality control materials based on the specific Ecstasy Assay cutoff.
Matrix	Human urine based	Human urine based
Analyte	Contains 6-AM and MDMA	Contains MDMA
Target Concentrations for 6-AM	Level 1: 5 ng/mL Level 2: 10 ng/mL Level 3: 15 ng/mL Level 4: 20 ng/mL	None
Preparation	Liquid – Ready to Use	Liquid – Ready to Use
Storage	2 – 8°C	2 – 8°C

Comparison of Control Features

Feature	Proposed Device Emit® II Plus 6-AM / Ecstasy Calibrators / Controls	Predicate Emit® II Plus Ecstasy Calibrators / Controls (k043028)
Indications For Use	Controls may be used as quality control materials based on the specific Emit® II Plus 6-Acetylmorphine and Emit® II Plus Ecstasy Assay cutoffs.	The Emit® II Plus Ecstasy Calibrators / Controls are used in the calibration of the Emit® II Plus Ecstasy Assay. These standards may also be used as quality control materials based upon the specific Ecstasy Assay cutoff.
Analyte	Contains 6-AM and MDMA	Contains MDMA
Positive Quality Control Level for Qualitative Analysis	Level 4	Level 4

J. Method Comparison:

Qualitative and Semiquantitative Results

Split sample method comparison was conducted and one-hundred five (105) unaltered human urine samples were analyzed by the Emit® II Plus 6-Acetylmorphine Assay vs. GC/MS. The results are presented below:

Emit® II Plus 6-Acetylmorphine Assay vs. GC/MS

		GC/MS				
		LOW NEG Less than 50% below the cutoff (<5 ng/mL)	NEG Within 50% below the cutoff (5.0 ~ 9.9 ng/mL)	POS Within 50% above the cutoff (10.0 ~ 15 ng/mL)	HIGH POS Greater than 50% above the cutoff (>15 ng/mL)	% Agreement
Qualitative Summary						
Emit®	POS	0	1	15	34	98%
	NEG	49	6	0	0	100%
Semiquantitative Summary						
Emit®	POS	0	1	15	34	98%
	NEG	49	6	0	0	100%

Discordant Result Summary

Cutoff Value (10 ng/mL)	Qualitative Result (POS/NEG)		Semiquantitative Result (ng/mL)	
	Emit® Assay	GC/MS	Emit® Assay	GC/MS
Sample # 55	+	-	16.3	7.8

K. Conclusion:

The information provided in this pre-market notification, demonstrates the Emit® II Plus 6- Acetylmorphine Assay and the Emit® 6-AM / Ecstasy Calibrators / Controls are substantially equivalent to the legally marketed predicate devices for their general intended use. Substantial equivalence was demonstrated through comparison of intended use and technological features to the commercially available predicate devices and confirmed by gas chromatography/mass spectrometry (GC/MS), an independent analytical method. The information given in this pre-market notification provides reasonable assurance that the Emit® II Plus 6- Acetylmorphine Assay and Calibrators /Controls are safe and effective for their stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

MAR 18 2011

Siemens Healthcare Diagnostics Inc.
c/o Ms. Janet Fose
Regulatory Technical Specialist, Regulatory Affairs
P.O. Box 6101, Mailbox 514
Newark, DE 19714-6101

Re: k102779
Trade/Device Name: Emit® II Plus 6-Acetylmorphine Assay and Emit® II Plus 6-AM / Ecstasy Calibrator / Control Levels 1 - 4

Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: Class II
Product Code: DJG, DKB and DIF
Dated: February 10, 2011
Received: February 11, 2011

Dear Ms. Fose:

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 Parts 801 and 809), 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 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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney 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

510(k) Number (if known): k102779

Device Name: Emit® II Plus 6-Acetylmorphine Assay
Emit® II Plus 6-AM / Ecstasy Calibrator /Control Level 1
Emit® II Plus 6-AM / Ecstasy Calibrator /Control Level 2
Emit® II Plus 6-AM / Ecstasy Calibrator /Control Level 3
Emit® II Plus 6-AM / Ecstasy Calibrator /Control Level 4

Indications For Use:

Emit® II Plus 6-Acetylmorphine Assay
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Emit® II Plus 6-AM/Ecstasy Calibrators/Controls
Calibrators are used in the calibration of the Emit® II Plus 6-Acetylmorphine and Emit® II Plus Ecstasy Assays.

Controls may be used as quality control materials based on the specific Emit® II Plus 6-Acetylmorphine and Emit® II Plus Ecstasy Assay cutoffs.

Prescription Use ___x___ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

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

510(k) k102779