DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 2, 2017

MP Biomedicals, LLC
Sean R. Gemmill, MS, RAC
Director of Regulatory Affairs
1429 Rollins Road
Burlingame, California 94010

Re: k162395
Trade/Device Name: MP DOA-10 Panel Test Cup, MP DOA-11 Panel Test Cup
Regulation Number: 21 CFR 862.3250
Regulation Name: Cocaine and cocaine metabolite test system
Regulatory Class: Class II
Product Code: DIO, DIS, DJG, DJR, DKZ, JXM, LAF, LCM, LDJ
Dated: May 9, 2017
Received: May 10, 2017

Dear Mr. Gemmill:

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 Part 801 and Part 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 regulation (21 CFR Part 801 and Part 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,

Courtney H. Lias -S

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)*
K162395

Device Name
MP DOA-10 Panel Test Cup
MP DOA-11 Panel Test Cup

Indications for Use *(Describe)*
The MP DOA-10 Panel Test Cup and the MP DOA-11 Panel Test Cup are immunochromatographic one-step in-vitro tests intended for the qualitative detection of up to ten or eleven different drug substances, respectively, in human urine at the following cut-off levels: amphetamine, 1000 ng/ml; barbiturate, 300 ng/ml; benzodiazepine, 300 ng/ml; buprenorphine, 10 ng/ml; cannabinoid, 50 ng/ml.; cocaine, 300 ng/ml; methadone, 300 ng/ml; methamphetamine, 1000 ng/ml; opiates, 300/2000 ng/ml; oxycodone, 100 ng/ml and phencyclidine, 25 ng/ml. Only one cutoff concentration will be included per analyte per device.

The MP DOA-10 Panel Test Cup and the MP DOA-11 Panel Test Cup may be used in a point-of-care (POC) setting and will provide preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the Substance Abuse Mental Health Services Administration (SAMSHA). Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

This summary of 510(k) safety and effectiveness is submitted in accordance with 21 CFR 807.92.

The assigned 510(k) number is: **K162395**

1. Date: May 24, 2017

2. Submitter:

Rapid Diagnostics
Division of MP Biomedicals, LLC
1429 Rollins Road
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3. Contact Person:

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Director of Regulatory Affairs
MP Biomedicals, LLC
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Santa Ana, CA 92707
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FAX: (949) 859-5010

4. Establishment Registration #: 2954282

5. Device Name:

Common Name: Multi Drugs of Abuse Test Cup

Trade or Proprietary Name: MP DOA-10 Panel Test Cup
MP DOA-11 Panel Test Cup

6. Classification: Class II medical as defined by FDA product codes and the Code of Federal Regulations (CFRs):

Product Code	Regulatory Description	Device Class	Regulation Section	Review Panel
DKZ	Amphetamine test system	II	862.3100	Toxicology (91)
DIS	Barbituate test system	II	862.3150	Toxicology (91)
JXM	Benzodiazepine test system	II	862.3170	Toxicology (91)
LDJ	Cannabinoid test system	II	862.3870	Toxicology (91)
DIO	Cocaine and cocaine metabolite test system	II	862.3250	Toxicology (91)
DJR	Methadone test system	II	862.3620	Toxicology (91)
LAF	Methamphetamine test system	II	862.3610	Toxicology (91)
LCM	Amphetamine test system, Phencyclidine	II	862.3100	Toxicology (91)
DJG	Opiate test system	II	862.3650	Toxicology (91)

7. Description of the Device:

The Rapid Diagnostics MP DOA-10 Panel Test Cup and MP DOA-11 Panel Test Cup are competitive binding, lateral flow immunochromatographic *iv-vitro* assays for the qualitative and simultaneous detection of amphetamines, barbiturates, benzodiazepines, buprenorphine, cannabinoids, cocaine, methadone, methamphetamine, opiates, oxycodone and phencyclidine, in human urine samples. MP DOA-10 Panel Test Cup and MP DOA-11 Panel Test Cup detects each of the analytes on separate strips. A positive urine sample will not generate a colored line for the specific drug tested in the designated region. A negative urine sample containing amphetamine, barbiturates, benzodiazepines, buprenorphine, cannabinoids, cocaine, methadone, methamphetamine, opiates, oxycodone or phencyclidine below the designated cutoff levels will generate a colored line in the designated test region for the drug. To serve as a procedural control, a colored line will always appear at the control region. Drug substances detected and cut-off levels are included in the following table:

Drug Identifier	**Cut-off Level (ng/ml)**
Amphetamine (AMP)	1000
Barbiturates (BAR)	300
Benzodiazepine (BZD)	300
Buprenorphine (BUP)	10
Cannabinoids (THC)	50
Cocaine (COC)	300
Methadone (MTD)	300
Methamphetamine (MAMP)	1000
Opiates	300
Opiates II	2000
Oxycodone (OXY)	100
Phencyclidine (PCP)	25

Configurations of the MP DOA-10 Panel Test Cup and MP DOA-11 Panel Test Cup can consist of any combination of up to 10 or 11 drug analyte test strips respectively, depending on the cup size. The test provides only preliminary test results and a more specific alternative chemical method must be used in order to obtain a confirmed analytical results. GC/MS is the preferred confirmatory method.

8. Indications for Use

The MP DOA-10 Panel Test Cup and the MP DOA-11 Panel Test Cup are immunochromatographic one-step in-vitro tests intended for the qualitative detection of up to ten or eleven different drug substances, respectively, in human urine at the following cut-off levels: amphetamine, 1000 ng/ml; barbiturate, 300 ng/ml; benzodiazepine, 300 ng/ml; buprenorphine, 10 ng/ml; cannabinoid, 50 ng/ml.; cocaine, 300 ng/ml; methadone, 300 ng/ml; methamphetamine, 1000 ng/ml; opiates, 300/2000 ng/ml; oxycodone, 100 ng/ml and phencyclidine, 25 ng/ml. Only one cutoff concentration will be included per analyte per device.

The MP DOA-10 Panel Test Cup and the MP DOA-11 Panel Test Cup may be used in a point-of-care (POC) setting and will provide preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the Substance Abuse Mental Health Services Administration (SAMSHA). Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

9. Predicate Devices

The following 510(k) cleared devices belong to Rapid Diagnostics; Rapid Drugs of Abuse Single and Multiple Test Panels (K003809), MICROMEDIC Drugs of Abuse Panel Test (K033566) and RapidBUP Test Strip / RapidOXY Test Strip (K051958). These previously cleared drugs of abuse test strip and drugs of abuse test panels are predicate devices to the MP DOA-10 Panel Test Cup and MP DOA-11 Panel Test Cups of this Pre-Market Notification.

10. Substantial Equivalence Information

The MP DOA-10 Panel Test Cup and MP DOA-11 Panel Test Cup are a "modified" product format derived from previously FDA cleared single and multi-panel DOA tests. The modification of the subject device, MP DOA-10 Panel Test Cup and the MP DOA-11 Panel Test Cup offers the previously 510(k) cleared drugs of abuse tests in a test cup format. The following 510(k) cleared devices; Rapid Drugs of Abuse Single and Multiple Test Panels (K003809), MICROMEDIC Drugs of Abuse Panel Test (K033566) and RapidBUP Test Strip/RapidOXY Test Strip (K051958), to which substantial equivalence is claimed, belong to Rapid Diagnostics. The subject devices in its modified format of this submission are substantially equivalent to the previously cleared Rapid Diagnostics drugs of abuse tests.

11. Performance

A comparison study was conducted to verify that there is no performance difference of the DOA Test Strips and DOA Test Cups when exposed to a human urine specimen for 20 seconds vs. 5 minutes. For each device format, three lots of product were tested over three drug cut-off concentration levels (-50%, + 50%, +300%) including a negative specimen. Testing was conducted utilizing three device formats; DOA Test Strips, DOA-10 Panel Test Cup and DOA-11 Panel Test Cups. During the conduct of this comparison study there were no observed test failures. 432/432 of the drug test strips passed, 360/360 of the MP DOA-10 Panel Test Cups passed and 396/396 of the MP DOA-11 Panel Test Cups passed per the pre-defined study acceptance criteria. An interfering drug analyte study was conducted using 198 MP DOA-11 Panel Test Cups (divided in 2 groups) and 180 MP DOA-10 Panel Test Cups (divided in 2 groups) over 3 lots of DOA Test Cups. Cut-off concentrations (-50%, +50%, +300%) for each drug analyte were assessed for interference. Following the addition of specimen at the 3 different concentrations, results at 5 and 10 minutes demonstrated no interference. Additional performance data of precision, reproducibility, interference, sensitivity and specificity of the specific analytes and test devices were reported in previously cleared 510(k) Pre-Market Notifications belonging to Rapid Diagnostics as outlined in the following table:

Rapid Diagnostics Drugs of Abuse Tests - Performance Data References		
Drug Identifier	**Cut-off Level (ng/ml)**	**510(k) Reference**
Amphetamine	1000	K033566, K003809
Barbiturates (secobarbital)	300	K033566, K030211
Benzodiazepine (oxezepam)	300	K033566, K003809
Buprenorphine	10	K051958
Cannabinoids	50	K033566, K003809
Cocaine	300	K033566, K003809
Methadone	300	K033566, K023252
Methamphetamine	1000	K033566, K003809
Opiates	300	K033566, K003809
Opiates II	2000	K033566, K020716
Oxycodone	100	K051958
Phencyclidine	25	K033566, K003809