March 24, 2021

Safecare Biotech(Hangzhou)Co., Ltd.
℅ Joe Shia, Manager
LSI International
504 E Diamond Ave., Suite I
Gaithersburg, MD 20877

Re: K202453
Trade/Device Name: SAFECARE Multi-Drug Urine Test Cup
SAFECARE Multi-Drug Urine Test Dip-Card
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine Test System
Regulatory Class: Class II
Product Code: NFT, NFW, NFY, NGG, NGI, NFV, NGL, PTH, PTG, QAW, QBF, NGM
Dated: August 25, 2020
Received: August 27, 2020

Dear Joe Shia:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie Kelm, Ph.D.
Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k202453

Device Name
SAFECARE® Multi-Drug Urine Test Dip Card
SAFECARE® Multi-Drug Urine Test Cup

Indications for Use *(Describe)*
SAFECARE® Multi-Drug Urine Test Dip Card is competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, Nortriptyline d-Propoxyphene and 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP) in human urine at the cutoff concentrations of:

Drug(Identifier)	Cut-off level
Amphetamine	500ng/mL
Oxazepam	300 ng/mL
Cocaine	150ng/mL
Marijuana	50 ng/mL
Methamphetamine	500ng/mL
Morphine	300ng/mL
Oxycodone	100 ng/mL
Secobarbital	300 ng/mL
Buprenorphine	10 ng/mL
Methylenedioxy-methamphetamine	500 ng/mL
Phencyclidine	25 ng/mL
Methadone	300 ng/mL
Nortriptyline	1000 ng/mL
d-Propoxyphene	300 ng/mL
2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine	300 ng/mL

Configuration of SAFECARE® Multi-Drug Urine Test Dip Card can consist of any combination of the above listed drug analytes.

The test may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.
The tests are intended for over-the-counter use.

SAFECARE® Multi-Drug Urine Test Cup is competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, Nortriptyline d-Propoxyphene and 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP) in human urine at the cutoff concentrations of:

Drug(Identifier)	Cut-off level
Amphetamine	500ng/mL
Oxazepam	300 ng/mL

Cocaine	150ng/mL
Marijuana	50 ng/mL
Methamphetamine	500ng/mL
Morphine	300ng/mL
Oxycodone	100 ng/mL
Secobarbital	300 ng/mL
Buprenorphine	10 ng/mL
Methylenedioxy-methamphetamine	500 ng/mL
Phencyclidine	25 ng/mL
Methadone	300 ng/mL
Nortriptyline	1000 ng/mL
d-Propoxyphene	300 ng/mL
2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine	300 ng/mL

Configuration of SAFECARE® Multi-Drug Urine Test Cup can consist of any combination of the above listed drug analytes.

The test may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.
The tests are intended for over-the-counter use.

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

510(k) Number: k202453

1. Date: March 18, 2021

2. Submitter: Safecare Biotech (Hangzhou) Co. Ltd.
18 Haishu Road, Yuhang District
Hangzhou, China

3. Contact person: Joe Shia
LSI International Inc.
504E Diamond Ave., Suite I
Gaithersburg, MD 20877
Telephone: 240-505-7880
Email: shiajl@yahoo.com

4. Device Name: SAFECARE® Multi-Drug Urine Test Dip Card
SAFECARE® Multi-Drug Urine Test Cup

Classification: Class 2

Product Code	Classification	Regulation Section	Panel
NFT Amphetamine	II	21 CFR § 862.3100, Amphetamine Test System	Toxicology (91)
NFW Cannabinoids	II	21 CFR § 862.3870, Cannabinoids Test System	Toxicology (91)
NFY Cocaine	II	21 CFR § 862.3250, Cocaine and Cocaine Metabolites Test System	Toxicology (91)
NGG Methamphetamine	II	21 CFR § 862.3610, Methamphetamine Test System	Toxicology (91)
NGI Morphine	II	21 CFR § 862.3640, Morphine Test System	Toxicology (91)
NFV Oxazepam	II	21 CFR § 862.3170, Benzodiazepine Test System	Toxicology (91)
NGL Oxycodone	II	21 CFR § 862.3650, Opiate Test System	Toxicology (91)
PTH Secobarbital	II	21 CFR § 862.3150, Barbiturate Test System	Toxicology (91)
NGL Buprenorphine	II	21 CFR § 862.3650, Opiate Test System	Toxicology (91)
NGG Methylenedioxy-methamphetamine	II	21 CFR § 862.3610, Methamphetamine Test System	Toxicology (91)
NGM Phencyclidine	unclassified	Enzyme Immunoassay Phencyclidine	Toxicology (91)
PTG Methadone	II	21 CFR § 862.3620, Methadone Test System	Toxicology (91)
QAW Nortriptyline	II	21 CFR, 862.3910 Tricyclic Antidepressant Drugs Test System	Toxicology (91)
QBF Propoxyphene	II	21 CFR, 862.3700 Propoxyphene Test System	Toxicology (91)

Product Code	Classification	Regulation Section	Panel
PTG 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine	II	21 CFR § 862.3620, Methadone Test System	Toxicology (91)

5. Predicate Device

   The SAFECARE® Multi-Drug Urine Test Dip Card and SAFECARE® Multi-Drug Urine Test Cup (K201120)

6. Intended Use

   SAFECARE® Multi-Drug Urine Test Dip Card is competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, Nortriptyline d-Propoxyphene and 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP) in human urine at the cutoff concentrations of:

Drug (Identifier)	Cut-off level
Amphetamine	500ng/mL
Oxazepam	300 ng/mL
Cocaine	150ng/mL
Marijuana	50 ng/mL
Methamphetamine	500ng/mL
Morphine	300ng/mL
Oxycodone	100 ng/mL
Secobarbital	300 ng/mL
Buprenorphine	10 ng/mL
Methylenedioxy-methamphetamine	500 ng/mL
Phencyclidine	25 ng/mL
Methadone	300 ng/mL
Nortriptyline	1000 ng/mL
d-Propoxyphene	300 ng/mL
2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine	300 ng/mL

Configuration of SAFECARE® Multi-Drug Urine Test Dip Card can consist of any combination of the above listed drug analytes.

The test may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.
The tests are intended for over-the-counter use.

SAFECARE® Multi-Drug Urine Test Cup is competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, Nortriptyline d-

Propoxyphene and 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP) in human urine at the cutoff concentrations of:

Drug (Identifier)	Cut-off level
Amphetamine	500ng/mL
Oxazepam	300 ng/mL
Cocaine	150ng/mL
Marijuana	50 ng/mL
Methamphetamine	500ng/mL
Morphine	300ng/mL
Oxycodone	100 ng/mL
Secobarbital	300 ng/mL
Buprenorphine	10 ng/mL
Methylenedioxy-methamphetamine	500 ng/mL
Phencyclidine	25 ng/mL
Methadone	300 ng/mL
Nortriptyline	1000 ng/mL
d-Propoxyphene	300 ng/mL
2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine	300 ng/mL

Configuration of SAFECARE® Multi-Drug Urine Test Cup can consist of any combination of the above listed drug analytes.

The test may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.
The tests are intended for over-the-counter use.

7. Device Description

   The SAFECARE® Dip Card Tests and SAFECARE® Cup Tests are immunochromatographic assays that use a lateral flow system for the qualitative detection of Amphetamine, Oxazepam, Cocaine, Cannabinoids, Methamphetamine, Morphine, Secobarbital, Methadone, Methylenedioxymethamphetamine, Oxycodone, Buprenorphine, Phencyclidine, Nortriptyline, Propoxyphen and 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (target analytes) in human urine. The products are single-use in vitro diagnostic devices, which come in the formats of Dip Cards or Cups. Each test kit contains a Test Device (in one of the two formats), a package insert and a urine cup for sample collection. Each test device is sealed with a desiccant in an aluminum pouch.

8. Substantial Equivalence Information

   A summary comparison of features of the SAFECARE® Dip Card Tests and SAFECARE® Cup Tests and the predicate devices is provided in following table.

Features Comparison of SAFECARE® Dip Card Tests and the Predicate Device

Item	Device	Predicate – K201120
Indication(s) for Use	For the qualitative determination of Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Cannabinoids in human urine.	Same
Similarities		
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative	Same
Specimen Type	Human Urine	Same
Intended Use	For over-the-counter	Same
Configurations	Dip Card	Same
Differences		
Calibrator and Cut-Off Values	Amphetamine (AMP): 500 ng/ml Oxazepam (BZO):300 ng/ml Cocaine (COC): 150 ng/ml 11-Nor-Δ^9-Tetrahydrocannabinol-9-COOH (THC):50 ng/ml Methamphetamine (MET): 500 ng/ml Morphine (MOP): 300ng/ml Secobarbital (BAR): 300 ng/ml Methadone (MTD): 300 ng/ml Methylenedioxymethamphetamine (MDMA): 500 ng/ml Oxycodone (OXY): 100 ng/ml Buprenorphine (BUP): 10 ng/ml Phencyclidine (PCP): 25 ng/ml Nortriptyline (TCA): 1000 ng/ml Propoxyphene (PPX): 300 ng/ml 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP): 300 ng/mL	Same as candidate device with exception of Amphetamine: 1000ng/mL Cocaine: 300ng/mL Methamphetamine: 1000ng/mL Morphine: 2000ng/mL

Features Comparison of SAFECARE® Cup Tests and the Predicate Devices

Item	Device	Predicate – K201120
Indication(s) for Use	For the qualitative determination of Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Cannabinoids in human urine.	Same
Similarities		
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative	Same
Specimen Type	Human Urine	Same
Intended Use	For over-the-counter	Same
Configurations	Cup	Cup
Differences		
Calibrator and Cut-Off Values	Amphetamine (AMP): 500 ng/ml Oxazepam (BZO):300 ng/ml Cocaine (COC): 150 ng/ml 11-Nor-$\triangle^9$-Tetrahydrocannabinol-9-COOH (THC):50 ng/ml Methamphetamine (MET): 500 ng/ml Morphine (MOP): 300ng/ml Secobarbital (BAR): 300 ng/ml Methadone (MTD): 300 ng/ml Methylenedioxymethamphetamine (MDMA): 500 ng/ml Oxycodone (OXY): 100 ng/ml Buprenorphine (BUP): 10 ng/ml Phencyclidine (PCP): 25 ng/ml Nortriptyline (TCA): 1000 ng/ml Propoxyphene (PPX): 300 ng/ml 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP): 300 ng/mL	Same as candidate device with exception of Amphetamine: 1000ng/mL Cocaine: 300ng/mL Methamphetamine: 1000ng/mL Morphine: 2000ng/mL

9. Test Principle

The SAFECARE® Dip Card Tests, and SAFECARE® Cup Tests are rapid tests for the qualitative detection of Amphetamine, Oxazepam, Cocaine, Cannabinoids, Methamphetamine, Morphine, Secobarbital, Methadone, Methylenedioxymethamphetamine, Oxycodone, Buprenorphine, Phencyclidine, Nortriptyline, Propoxyphen and 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine in urine samples. The tests are lateral flow chromatographic immunoassays. During testing, a urine specimen migrates upward by capillary action. If target drugs present in the urine specimen are below the cut-off concentration, it will not saturate the binding sites of its specific monoclonal mouse antibody coated on the particles. The antibody-coated particles will then be captured by immobilized drug-conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the target drug level exceeds its cutoff-concentration because it will saturate all the binding sites of the antibody coated on the particles. A band should form in the control region of the devices regardless of the presence of drug or metabolite in the sample to indicate that the tests have been performed properly.

10. Performance Characteristics

1. Analytical Performance

a. Precision

Precision studies were carried out for samples with concentrations of -100% cut off, -75% cut off, -50% cut off, -25% cut off, cut off, +25% cut off, +50% cut off, +75% cut off and +100% cut off. These samples were prepared by spiking drug in negative samples. Each drug concentration was confirmed by LC/MS. All sample aliquots were blindly labeled by the person who prepared the samples and didn't take part in the sample testing. For each concentration, tests were performed two runs per day for 25 days per device in a randomized order. The results obtained are summarized in the following tables for Amphetamine 500, Cocaine 150, Methamphetamine 500 and Morphine 300. Please refer to k182654 for precision data for Methylenedioxy-Methamphetamine, Oxycodone, Buprenorphine, Phencyclidine, Nortriptyline and Propoxyphene, and to k181968 for precision data for Oxazepam, Secobarbital and Methadone, and to k153646 for precision data for Cannabinoids and to k201120 for precision data for EDDP. The candidate device uses the same assays (same reagent pads) for these drugs as was cleared in k182654/k181968/k153646/k201120.

Amphetamine 500

Dip Card

Results / **Lot Number**	**-100% Cut-off**	**-75% Cut-off**	**-50% Cut-off**	**-25% Cut-off**	**Cut-off**	**Cut-off +25%**	**Cut-off +50%**	**Cut-off +75%**	**Cut-off +100%**
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-

Cup

Results / Lot Number	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100%
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-

Cocaine 150

Dip Card

Results / Lot Number	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100%
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-

Cup

Results / Lot Number	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100%
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-

Methamphetamine 500

Dip Card

Results / Lot Number	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100%
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-

Cup

Results / Lot Number	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100%
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-

Morphine 300

Dip Card

Results / Lot Number	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100%
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-

Cup

Results / Lot Number	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100%
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-

The cut-off values of 500 ng/mL, 150 ng/mL, 500 ng/mL, and 300 ng/mL for Amphetamine, Cocaine, Methamphetamine and Morphine are verified.

b. Linearity

Not applicable.

c. Stability

The devices are stable at 4-30 °C for 24 months based on the accelerated stability study at 50 °C and real time stability studies at 4°C and 30 °C.

d. Interference

Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and target drugs urine with concentrations at 25% below and 25% above Cut-Off levels. These urine samples were tested using three batches of each device. Compounds that showed no interference at a concentration of 100µg/mL, with the exception of albumin with no interference at a concentration of 100mg/dL and ethanol at 1% volume, are summarized in the following tables. There were no differences observed between the SAFECARE® Cup and Dip Card formats.

Acetominophen (4-Acetamidophenol)	Ecgonine methyl ester	D,L-Octopamine
Acetophenetidin	Erythromycin	Oxalic acid
N-Acetylprocainamide	β-Estradiol	Oxolinic acid
Acetylsalicylic acid	Ethanol (1% vol)	Oxymetazoline
Albumin (100mg/dL)	Fenoprofen	Papaverine
Aminopyrine	Furosemide	Penicillin-G
Amoxicillin	Gentisic acid	Perphenazine
Ampicillin	Hemoglobin	Phenelzine
Apomorphine	Hydralazine	Prednisone
Ascorbic acid	Hydrochlorothiazide	DL-Propranolol
Aspartame	Hydrocortisone	D-Pseudoephedrine
Atropine	O-Hydroxyhippuric acid	Quinine
Benzilic acid	3-Hydroxytyramine	Ranitidine
Benzoic acid	Ibuprofen	Salicylic acid

Bilirubin	D,L-Isoproterenol	Serotonin (5- Hydroxytyramine)
Chloralhydrate	Isoxsuprine	Sulfamethazine
Chloramphenicol	Ketamine	Sulindac
Chlorothiazide	Ketoprofen	Tetrahydrocortisone, 3-acetate
Chlorpromazine	Labetalol	Tetrahydrocortisone 3-(β-Dglucuronide)
Cholesterol	Loperamide	Tetrahydrozoline
Clonidine	Meperidine	Thiamine
Cortisone	Meprobamate	Thioridazine
(-) Cotinine	Methoxyphenamine	Triamterene
Creatinine	Nalidixic acid	DL-Tyrosine
Deoxycorticosterone	Naloxone	Trifluoperazine
Dextromethorphan	Naltrexone	Trimethoprim
Diclofenac	Naproxen	D L-Tryptophan
Diflunisal	Niacinamide	Tyramine
Digoxin	Nifedipine	Uric acid
Diphenhydramine	Norethindrone	Verapamil
Disopyramide	Noscapine	Zomepirac

e. Specificity

To test specificity, drug metabolites and other structure related compounds that are likely to cross-react in urine samples were tested using three batches of each device. The lowest concentration that caused a positive result for each compound are listed below for Amphetamine 500, Cocaine 150, Methamphetamine 500 and Morphine 300. Please refer to k182654 for Methylenedioxy-Methamphetamine, Oxycodone, Buprenorphine, Phencyclidine, Nortriptyline and Propoxyphene, and to k181968 for Oxazepam, Secobarbital and Methadone, and to k153646 for Cannabinoids and to k201120 for EDDP. There were no differences observed between the SAFECARE® Cup and Dip Card formats. The candidate device uses the same assays (same reagent pads) for these drugs as was cleared in k182654/k181968/k153646/k201120.

Amphetamine

Compounds	**Result Positive at(ng/ml)**	**% Cross-Reactivity**
l-Amphetamine	25000	2%
dl- Amphetamine	1500	33%
3,4-Methylenedioxyamphetamine (MDA)	2500	20%
Phentermine	1500	33%
Hydroxyamphetamine	8000	6%
β-Phenylethylamine	100000	0.5%
Tyramine	100000	0.5%
p-Hydroxynorephedrine	100000	0.5%
p-Hydroxyamphetamine	100000	0.5%
d/l-Norephedrine	100000	0.5%
d-Methamphetamine	>100,000	<0.5%
l-Methamphetamine	>100,000	<0.5%
Methylenedioxyethylamphetamine (MDE)	>100,000	<0.5%
Methylenedioxymethamphetamine(MDMA)	>100,000	<0.5%
Ephedrine	>100,000	<0.5%
Phenylpropanolamine	>100,000	<0.5%
(±)Phenylpropanolamine	>100,000	<0.5%
Benzphetamine	>100,000	<0.5%

Cocaine

Compounds	Result Positive at(ng/ml)	% Cross-Reactivity
Cocaine	375	40%
Cocaethylene	6250	2.4%
Ecgonine	16000	1 %
Ecgonine methyl ester	>100,000	<0.2%
Norcocaine	>100,000	<0.2 %

Methamphetamine

Compounds	Result Positive at(ng/ml)	% Cross-Reactivity
D-Amphetamine	25000	2%
L- Amphetamine	37500	1%
Chloroquine	10000	5%
(+/-)-Ephedrine	25000	2%
D/L-Methamphetamine	500	100%
L-Methamphetamine	10000	5%
(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	500	100%
3,4-Methylenedioxyamphetamine(MDA)	500	100%
Methylenedioxymethamphetamine(MDMA)	2000	25%
β-Phenylethylamine	25000	2%
Trimethobenzamide	5000	10%
d/l-Amphetamine	75000	1%
p-Hydroxymethamphetamine	15000	3%
Mephentermine	25000	2%
(1R,2S)-(-)-Ephedrine	50000	1%
l-Phenylephrine	100000	0.5%
(-)-Methamphetamine	12500	2%

Morphine

Compounds	Result Positive at(ng/ml)	% Cross-Reactivity
Normorphine	300	100%
s-Monoacetylmorphine	300	100%
Codeine	300	100%
Ethyl Morphine	100	300%
Heroin	300	100%
Hydrocodone	5000	6%
Hydromorphone	1000	30%
Morphinie-3-β-d-glucuronide	1000	30%
Oxycodone	>100000	<0.3%
Oxymorphone	100000	0.3%
Thebaine	3000	10%
Levorphanol	10000	3%
6-Monoacetylmorphine (6-MAM)	150	200%
Norcodeine	6250	5%
Procaine	150000	0.2%

f. Effect of Urine Specific Gravity and Urine pH

To investigate the effect of urine specific gravity and urine pH, urine samples, with 1.000 to 1.035 specific gravity or urine samples with pH 4 to 9 were spiked with target drugs at 25% below and 25% above Cut-Off levels. These samples were tested using three lots of each device. Results were all positive for samples at and above +25% Cut-Off and all negative for samples at and below -25% Cut-Off. There were no differences observed between the SAFECARE® Cup and Dip Card formats.

2. Comparison Studies

Method comparison studies for the SAFECARE® Dip Card Tests and the SAFECARE® Cup Tests were performed in-house with three laboratory assistants for each device. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples for each drug. The samples were blind labeled and compared to LC/MS results. The results are presented in the tables below for Amphetamine 500, Cocaine 150, Methamphetamine 500 and Morphine 300. Please refer to k182654 for Methylenedioxy-Methamphetamine, Oxycodone, Buprenorphine, Phencyclidine, Nortriptyline and Propoxyphene, and to k181968 for Oxazepam, Secobarbital and Methadone, and to k153646 for Cannabinoids and to k201120 for EDDP. The candidate device uses the same assays (same reagent pads) for these drugs as was cleared in k182654/ k181968/ k153646 and k201120.

Amphetamine 500

Dip Card		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	1	20	20
	Negative	10	10	19	0	0
Viewer B	Positive	0	0	0	19	20
	Negative	10	10	20	1	0
Viewer C	Positive	0	0	1	20	20
	Negative	10	10	19	0	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Dip Card Viewer Results
Viewer A	LM8554	498	Positive
Viewer C	LM8554	498	Positive
Viewer B	LM1169	502	Negative

Cup		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	0	19	20
	Negative	10	10	20	1	0
Viewer B	Positive	0	0	1	20	20
	Negative	10	10	19	0	0
Viewer C	Positive	0	0	0	19	20
	Negative	10	10	20	1	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Cup Viewer Results
Viewer B	LM8561	498	Positive
Viewer A	LM1497	502	Negative
Viewer C	LM1497	502	Negative

Cocaine 150

Dip Card		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	1	20	20
	Negative	10	10	19	0	0
Viewer B	Positive	0	0	0	19	20
	Negative	10	10	20	1	0
Viewer C	Positive	0	0	1	20	20
	Negative	10	10	19	0	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Dip Card Viewer Results
Viewer A	LM8739	148	Positive
Viewer C	LM8739	148	Positive
Viewer B	LM7119	152	Negative

Cup		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	0	19	20
	Negative	10	10	20	1	0
Viewer B	Positive	0	0	1	20	20
	Negative	10	10	19	0	0
Viewer C	Positive	0	0	0	20	20
	Negative	10	10	20	0	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Cup Viewer Results
Viewer B	LM4418	148	Positive
Viewer A	LM1485	152	Negative

Methamphetamine 500

Dip Card		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	1	18	20
	Negative	10	10	19	2	0
Viewer B	Positive	0	0	2	19	20
	Negative	10	10	18	1	0
Viewer C	Positive	0	0	0	18	20
	Negative	10	10	20	2	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Dip Card Viewer Results
Viewer A	LM6106	467	Positive
Viewer B	LM7710	464	Positive
Viewer B	LM6106	467	Positive
Viewer A	LM7165	513	Negative
Viewer A	LM6198	511	Negative
Viewer B	LM7165	513	Negative
Viewer C	LM7165	513	Negative
Viewer C	LM6198	511	Negative

Cup		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	19	20
	Negative	10	10	18	1	0
Viewer B	Positive	0	0	1	18	20
	Negative	10	10	19	2	0
Viewer C	Positive	0	0	1	19	20
	Negative	10	10	19	1	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Cup Viewer Results
Viewer A	LM3480	464	Positive
Viewer A	LM8436	467	Positive
Viewer B	LM3480	464	Positive
Viewer C	LM8436	467	Positive
Viewer A	LM5908	513	Negative
Viewer B	LM8727	511	Negative
Viewer B	LM5908	513	Negative
Viewer C	LM5908	513	Negative

Morphine 300

Dip Card		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	1	19	20
	Negative	10	10	19	1	0
Viewer B	Positive	0	0	1	20	20
	Negative	10	10	19	0	0
Viewer C	Positive	0	0	2	19	20
	Negative	10	10	18	1	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Dip Card Viewer Results
Viewer A	LM4260	280	Positive
Viewer B	LM4260	280	Positive
Viewer C	LM4260	280	Positive
Viewer C	LM9616	281	Positive

Viewer A	LM2412	305	Negative
Viewer C	LM4067	306	Negative

Cup		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	1	20	20
	Negative	10	10	19	0	0
Viewer B	Positive	0	0	2	19	20
	Negative	10	10	18	1	0
Viewer C	Positive	0	0	0	19	20
	Negative	10	10	20	1	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Cup Viewer Results
Viewer A	LM8592	280	Positive
Viewer B	LM8592	280	Positive
Viewer B	LM1718	281	Positive
Viewer B	LM7813	305	Negative
Viewer C	LM1916	306	Negative

Lay-user study:

A lay user study was performed at three intended user sites with 310 lay persons for each device format. The lay users had diverse educational and professional backgrounds and ranged in age from 18 to > 50 years. Urine samples were prepared at the following concentrations; negative, +/-75%, +/-50%, +/-25% of the cutoff by spiking drugs into drug free-pooled urine specimens. The concentrations of the samples were confirmed by LC/MS. Each sample was aliquoted into individual containers and blind-labeled. Each participant was provided with the package insert, 1 blind labeled sample and a device. Each device was tested. Typical results are shown below.

AMP500:

% of Cutoff	Number of samples	Drug Concentration by LC/MS (ng/mL)	Lay person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	125	0	20	100
-50% Cutoff	170	250	0	170	100
-25% Cutoff	20	375	2	18	90
+25% Cutoff	20	625	19	1	95
+50% Cutoff	40	750	40	0	100
+75% Cutoff	20	878	20	0	100

COC150:

% of Cutoff	Number of samples	Drug Concentration by LC/MS(ng/mL)	Lay person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	38	0	20	100
-50% Cutoff	170	75	0	170	100
-25% Cutoff	20	113	2	18	90
+25% Cutoff	20	188	19	1	95
+50% Cutoff	40	225	40	0	100
+75% Cutoff	20	263	20	0	100

THC:

% of Cutoff	Number of samples	Drug Concentration by LC/MS(ng/mL)	Lay person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	13	0	20	100
-50% Cutoff	170	25	0	170	100
-25% Cutoff	20	37	1	19	95
+25% Cutoff	20	62	19	1	95
+50% Cutoff	40	76	40	0	100
+75% Cutoff	20	87	20	0	100

BAR:

% of Cutoff	Number of samples	Drug Concentration by LC/MS(ng/mL)	Lay person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	74	0	20	100
-50% Cutoff	170	151	0	170	100
-25% Cutoff	20	226	2	18	90
+25% Cutoff	20	373	18	2	90
+50% Cutoff	40	450	40	0	100
+75% Cutoff	20	526	20	0	100

BZO:

% of Cutoff	Number of samples	Drug Concentration by LC/MS(ng/mL)	Lay person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	75	0	20	100
-50% Cutoff	170	151	0	170	100
-25% Cutoff	20	224	2	18	90
+25% Cutoff	20	375	19	1	95
+50% Cutoff	40	452	40	0	100
+75% Cutoff	20	524	20	0	100

MET500:

% of Cutoff	Number of samples	Drug Concentration by LC/MS(ng/mL)	Lay person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	124	0	20	100
-50% Cutoff	170	251	0	170	100
-25% Cutoff	20	375	2	18	90
+25% Cutoff	20	625	19	1	95
+50% Cutoff	40	750	40	0	100
+75% Cutoff	20	877	20	0	100

MTD:

% of Cutoff	Number of samples	Drug Concentration by LC/MS(ng/mL)	Lay person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	74	0	20	100
-50% Cutoff	170	152	0	170	100
-25% Cutoff	20	225	2	18	90
+25% Cutoff	20	376	18	2	90
+50% Cutoff	40	451	40	0	100
+75% Cutoff	20	524	20	0	100

MOP300:

% of Cutoff	Number of samples	Drug Concentration by LC/MS(ng/mL)	Lay person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	75	0	20	100
-50% Cutoff	170	151	0	170	100
-25% Cutoff	20	225	1	19	95
+25% Cutoff	20	376	18	2	90
+50% Cutoff	40	452	40	0	100
+75% Cutoff	20	525	20	0	100

MDMA:

% of Cutoff	Number of samples	Drug Concentration by LC/MS(ng/mL)	Lay person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	124	0	20	100
-50% Cutoff	170	250	0	170	100
-25% Cutoff	20	377	2	18	90
+25% Cutoff	20	622	18	2	90
+50% Cutoff	40	749	40	0	100
+75% Cutoff	20	874	20	0	100

OXY:

% of Cutoff	Number of samples	Drug Concentration by LC/MS(ng/mL)	Lay person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	25	0	20	100
-50% Cutoff	170	50	0	170	100
-25% Cutoff	20	75	1	19	95
+25% Cutoff	20	124	18	2	90
+50% Cutoff	40	151	40	0	100
+75% Cutoff	20	175	20	0	100

BUP:

% of Cutoff	Number of samples	Drug Concentration by LC/MS(ng/mL)	Lay person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	3	0	20	100
-50% Cutoff	170	5	0	170	100
-25% Cutoff	20	8	2	18	90
+25% Cutoff	20	13	18	2	90
+50% Cutoff	40	15	40	0	100
+75% Cutoff	20	18	20	0	100

PCP:

% of Cutoff	Number of samples	Drug Concentration by LC/MS(ng/mL)	Lay person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	6	0	20	100
-50% Cutoff	170	13	0	170	100
-25% Cutoff	20	19	2	18	90
+25% Cutoff	20	31	18	2	90
+50% Cutoff	40	38	40	0	100
+75% Cutoff	20	44	20	0	100

TCA:

% of Cutoff	Number of samples	Drug Concentration by LC/MS(ng/mL)	Lay person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	252	0	20	100
-50% Cutoff	170	501	0	170	100
-25% Cutoff	20	752	1	19	95
+25% Cutoff	20	1255	19	1	95
+50% Cutoff	40	1503	40	0	100
+75% Cutoff	20	1751	20	0	100

PPX:

% of Cutoff	Number of samples	Drug Concentration by LC/MS(ng/mL)	Lay person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	75	0	20	100
-50% Cutoff	170	150	0	170	100
-25% Cutoff	20	225	2	18	90
+25% Cutoff	20	374	18	2	90
+50% Cutoff	40	452	40	0	100
+75% Cutoff	20	523	20	0	100

EDDP:

% of Cutoff	Number of samples	Drug Concentration by LC/MS(ng/mL)	Lay person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	75	0	20	100
-50% Cutoff	170	150	0	170	100
-25% Cutoff	20	224	1	19	95
+25% Cutoff	20	374	18	2	90
+50% Cutoff	40	450	40	0	100
+75% Cutoff	20	524	20	0	100

Lay-users were also given surveys on the ease of understanding the package insert instructions. All lay users indicated that the device instructions can be easily followed. A Flesch-Kincaid reading analysis was performed on each package insert and the scores revealed a reading Grade Level of 7.

3. Clinical Studies

Not applicable.

11. Conclusion

Based on the test principle and acceptable performance characteristics including precision, cut-off, interference, specificity, method comparison, and lay-user studies of the devices, it's concluded that the SAFECARE® Dip Card Tests and SAFECARE® Cup Tests are substantially equivalent to the predicate.