SEP 1 5 2003

510(k) Summary

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

The assigned 510(k) number is: K023837

1. Date of Summary: Nov. 14, 2002
2. Submitted by: Princeton BioMeditech Corporation
   4242 U.S. Route 1, Monmouth Jct., NJ 08852
   PHONE 732-274-1000
   FAX 732-274-1010
   Contact Person: Jemo Kang, Ph.D., Director
3. Device Name
   Trade Names: Stick: Status Stik™ THC/OPI/COC/MET & MDMA, AccuSign®Stik THC/OPI/COC/MET & MDMA, AccuStik™ DOA4
   Card: AccuSign® DOA4, Status DS™ DOA4
   Strip: AccuStrip™ DOA4
   Common or Usual Name: Immunoassay for detection of THC, opiates, cocaine, and methamphetamine, 3,4-methylenedioxymethamphetamine (MDMA) in urine
   Classification Name: Drugs of Abuse Analysis Systems, Toxicology (91DKE, 91DJG, 91DIO for Enzyme Immunoassay, 91LAG for HPLC)
4. Identification of legally marketed device to which claims equivalence: Status Stik™ THC/OPI/COC/MET; k014193
5. Device Description: Status Stik™ THC/OPI/COC/MET & MDMA is simple one step immunochromatographic test for the rapid, qualitative, simultaneous detection of THC, opiates, cocaine, methamphetamine and 3,4-methylenedioxymethamph- etamine.
6. Intended Use: Status Stik™ THC/OPI/COC/MET & MDMA is designed for the qualitative detection of THC at the cutoff of 50 ng/mL 11-nor-Δ^9-THC-9-carboxylic acid, opiates at the cutoff of 2000 ng/mL morphine, cocaine at the cutoff of 300 ng/mL benzoylecgonine, and methamphetamine and MDMA at the cutoff of 500 ng/mL d-methamphetamine and MDMA in human urine to assist in screening of drugs of abuse samples. For *in vitro* Diagnostic Use. This test provides only a preliminary analytical result and a more specific alternative chemical method must be used to obtain a confirmed analytical result and that GC/MS is the preferred confirmatory method.
7. Substantial Equivalence: Status Stik™ THC/OPI/COC/MET & MDMA is substantially equivalent to the k014193, Status Stik™ THC/OPI/COC/MET. Both products use the same assay principle and are immunochromatographic assays to detect THC, opiates, cocaine, methamphetamine qualitatively. The difference is that Status Stik™ THC/OPI/COC/MET detects methamphetamine at 1000 ng/mL and MDMA at 2000 ng/mL, while Status Stik™ THC/OPI/COC/MET & MDMA detects both methamphetamine and MDMA at 500 ng/mL.

Conclusion: The device is substantially equivalent to the legally marketed device, k014193, Status Stik™ THC/OPI/COC/MET.

510(k) Summary

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

The assigned 510(k) number is: k023837

1. Date of Summary: Nov 15, 2002

2. Submitted by: Princeton BioMeditech Corporation
   4242 U.S. Route 1, Monmouth Jct., NJ 08852
   PHONE 732-274-1000
   FAX 732-274-1010
   Contact Person: Jemo Kang, Ph.D., Director

3. Device Name
   Trade Names: LifeSign® Home Drug Test (Marijuana/Opiates/Cocaine/Ecstasy & MET)
   Common or Usual Name: Immunoassay for detection of THC, opiates, cocaine, methamphetamine and 3,4-methlyenedioxymethamphetamine (MDMA) in urine
   Classification Name: Drugs of Abuse Analysis Systems, Toxicology (91DKE, 91DJG, 91DIO for Enzyme Immunoassay, 91LAG for HPLC)
4. Identification of legally marketed device to which claims equivalence: LifeSign® Home Drug Test (THC/OPI/COC/MET); k014193
5. Device Description: LifeSign® Home Drug Test (Marijuana/Opiates/Cocaine/Ecstasy & MET) is simple one step immunochromatographic test for the rapid, qualitative, simultaneous detection of THC, opiates, cocaine, methamphetamine, and 3,4-methylenedioxymeth-amphetamine.

6. Intended Use: LifeSign® Home Drug Test is designed for the qualitative detection of THC at the cutoff of 50 ng/mL 11-nor-Δ^9-THC-9-carboxylic acid, opiates at the cutoff of 2000 ng/mL morphine, cocaine at the cutoff of 300 ng/mL benzoylecgonine, methamphetamine and MDMA at the cutoff of 500 ng/mL d-methamphetamine and MDMA in human urine to assist in screening of drugs of abuse samples. For *in vitro* Diagnostic Use. This test is intended for use in the home to assist in preventing drug abuse.
   This test provides only a preliminary analytical result and a more specific alternative chemical method must be used to obtain a confirmed analytical result and that GC/MS is the preferred confirmatory method.

7. Substantial Equivalence: LifeSign® Home Drug Test (Marijuana/Opiates/Cocaine/Ecstasy) is substantially equivalent to the k014193, LifeSign® Home Drug Test (THC/OPI/COC/MET). Both products use the same assay principle and are immunochromatographic assays to detect THC, opiates, cocaine, methamphetamine qualitatively. The difference is that LifeSign® Home Drug Test (THC/OPI/COC/MET) detects methamphetamine at 1000 ng/mL and MDMA at 2000 ng/mL, while LifeSign® Home Drug Test (Marijuana/Opiates/Cocaine/Ecstasy & MET) detects both methamphetamine and MDMA at 500 ng/mL.

8. Consumer Study: In a consumer study, LifeSign® Home Drug Test (THC/OPI/ COC/ MET) showed over 95% overall accuracy. Since LifeSign® Home Drug Test (Marijuana/Opiates/Cocaine/Ecstasy) is the same test (principle, format, test protocol, the reading of test result etc.) except the antibody used for methamphetamine, no new consumer study was performed.

Conclusion: The device is substantially equivalent to the legally marketed device, k014193, LifeSign® Home Drug Test (Marijuana/Opiates/Cocaine/Ecstasy & MET). The product is safe in the hands of the lay user.

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2. Submitted by: Princeton BioMeditech Corporation
   4242 U.S. Route 1, Monmouth Jct., NJ 08852
   PHONE 732-274-1000
   FAX 732-274-1010
   Contact Person: Jemo Kang, Ph.D.
3. Device Name: Trade Names: Stick Device: Status Stik™ MET & MDMA, AccuSign® Stik MET & MDMA, AccuStik™ MET & MDMA
   Card Device: AccuSign® MET & MDMA, Status DS™ MET & MDMA
   Strip Test: AccuStrip™ MET & MDMA
   Common or Usual Name: Immunoassay for detection of methamphetamine and 3,4-Methylenedioxymethamphetamine (MDMA) in urine
   Classification Name: Drugs of Abuse Analysis Systems, Toxicology (91LAG for HPLC)
4. Identification of legally marketed device to which claims equivalence: k014092; Status Stik™ MET
5. Device Description: Status Stik™ MET & MDMA is simple one step immunochromatographic test for the rapid, qualitative detection methamphetamine and MDMA.
6. Intended Use: Status Stik™ MET & MDMA is designed for the qualitative detection of both methamphetamine and MDMA at the cutoff of 500 ng/mL in urine to assist in screening of drugs of abuse samples. For *In vitro* Diagnostic, Prescription Use. This test provides only a preliminary analytical result and a more specific alternative chemical method must be used to obtain a confirmed analytical result and that GC/MS is the preferred confirmatory method.
7. Substantial Equivalence: Status Stik™ MET & MDMA is substantially equivalent to the k014092, Status Stik™ MET. Both products use the same assay principle and immunochromatographic assay to detect methamphetamine qualitatively. The difference is that Status Stik™ MET detects methamphetamine at 1000 ng/ml and MDMA at 2000 ng/ml, while Status DS™ MET & MDMA detects both methamphetamine and MDMA at 500 ng/ml.

Conclusion: The device is substantially equivalent to a legally marketed device k014092,

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2. Submitted by: Princeton BioMeditech Corporation
   4242 U.S. Route 1, Monmouth Jct., NJ 08852
   PHONE 732-274-1000
   FAX 732-274-1010
   Contact Person: Jemo Kang, Ph.D.

3. Device Name: Trade Names: Life Sign® Home Drug Test (Ecstasy & MET)
   Common or Usual Name: Immunoassay for detection of methamphetamine and methylenedioxymethamphetamine (MDMA) in urine
   Classification Name: Drugs of Abuse Analysis Systems, Toxicology (91LAG for HPLC)

4. Identification of legally marketed device to which claims equivalence: k014192
   Life Sign® Home Drug Test (MET)

5. Device Description: Life Sign® Home Drug Test (Ecstasy & MET) is simple one step immunochromatographic test for the rapid, qualitative detection of methamphetamine and MDMA.

6. Intended Use: Life Sign® Home Drug Test (Ecstasy & MET) is designed for the qualitative detection of MDMA and methamphetamine at the cutoff of 500 ng/mL in urine to assist in screening of drugs of abuse samples at home or work place. For *In vitro* Diagnostic Use This test provides only a preliminary analytical result and a more specific alternative chemical method must be used to obtain a confirmed analytical result and that GC/MS is the preferred confirmatory method.

7. Substantial Equivalence: Life Sign® Home Drug Test (Ecstasy & MET) is substantially equivalent to the k0140192; Life Sign® Home Drug Test (MET). Both products use the same assay principle and immunochromatographic assay to detect methamphetamine qualitatively. The difference is that Life Sign® Home Drug Test (MET) detects methamphetamine at 1000 ng/ml and MDMA at 2000 ng/ml, while Life Sign® Home Drug Test (Ecstasy & MET) detects both methamphetamine and MDMA at 500 ng/ml.

8. Consumer Study: In a consumer study, LifeSign® Home Drug Test (MET) showed over 96% overall accuracy. Since LifeSign® Home Drug Test (Ecstasy & MET) is the same test (principle, format, test protocol, the reading of test result etc.) except the antibody used for methamphetamine, no new consumer study was performed.

Conclusion: The device is substantially equivalent to a legally marketed device k0140192, LifeSign® Home Drug Test (MET).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 1 5 2003

Jemo Kang, Ph.D., M.B.A.
Director
Princeton BioMeditech Corporation
4242 U.S. Route 1
Monmouth Junction, NJ 08852-1905

Re: k023837
Trade/Device Name: Status Stik™ THC/OPI/COC/MET & MDMA, AccuSign® Stik THC/OPI/COC/MET & MDMA, AccuStik® DOA 4, Status DS™ DOA 4, AccuSign® DOA 4, AccuStrip™ DOA 4
Status Stik™ MET & MDMA, AccuSign® Stik MET & MDMA, AccuStik® MET & MDMA, AccuSign® MET & MDMA, Status DS™ MET & MDMA, AccuStrip™ MET & MDMA
LifeSign®Home Drug Test (Ecstasy/MET)
LifeSign®Home Drug Test (Marijuana/Opiates/Cocaine/Ecstasy & MET)
Regulation Number: 21 CFR 862.3610
Regulation Name: Methamphetamine test system
Regulatory Class: Class II
Product Code: LAF; LDJ; DJG; DIO
Dated: June 19, 2003
Received: June 19, 2003

Dear Dr. Kang:

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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K023837

Device Name: Status Stik™ MET & MDMA, AccuSign®Stik MET & MDMA, AccuStik™ MET & MDMA, AccuSign® MET & MDMA, Status DS™ MET & MDMA, AccuStrip™ MET & MDMA

Indications For Use:

Immunoassay for the qualitative detection of methamphetamine and 3,4-methylenedioxy-methamphetamine (MDMA) at the cut-off of 500 ng/mL in urine to assist in screening of drugs of abuse samples. For *In vitro* Diagnostic Use

This test provides only a preliminary analytical result and a more specific alternative chemical method must be used to obtain a confirmed analytical result and that GC/MS is the preferred confirmatory method.

Trade Names for each format

Stick: Status Stik™ MET & MDMA, AccuSign®Stik MET & MDMA, AccuStik™ MET & MDMA
Card: AccuSign® MET & MDMA, Status DS™ MET & MDMA
Strip: AccuStrip™ MET & MDMA

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Professional Use:___

Prescription Use: X OR Over The Counter Use: ___

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division Sign-Off for Jean Cooper

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K023837

510(k) Number (if known): K023837

Device Name: Status Stik™ THC/OPI/COC/MET & MDMA, AccuSign® Stik THC/OPI/COC/MET & MDMA, AccuStik® DOA 4, Status DS™ DOA 4, AccuSign® DOA 4

Indications For Use:

Immunoassay for the qualitative detection of THC metabolite, opiates, cocaine metabolite, methamphetamine and 3,4-methylenedioxymethamphetamine in urine to assist in screening of drugs of abuse. For *in vitro* Diagnostic Use
The detection cutoff concentrations are as follows:

THC	11-nor-Δ^9-THC-9-carboxylic acid	50 ng/ mL
OPI	Morphine	2000 ng/ mL
COC	Benzoylecgonine	300 ng/ mL
MET	D-Methamphetamine	500 ng/ mL
MDMA	3,4-Methylenedioxymethamphetamine	500 ng/ mL

This test provides only a preliminary analytical result and a more specific alternative chemical method must be used to obtain a confirmed analytical result and that GC/MS is the preferred confirmatory method.

Trade Names for each device format
Stick: Status Stik™ THC/OPI/COC/MET & MDMA, AccuSign®Stik THC/OPI/COC/MET & MDMA, AccuStik™ DOA4
Card: AccuSign® DOA4, Status DS™ DOA4
Strip: AccuStrip™ DOA4

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Professional Use:____

Prescription Use: X OR Over The Counter Use: ____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division Sign-Off for Jean Cooper

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K023837

510(k) Number (if known): K023837

Device Name: LifeSign®Home Drug Test (Ecstasy/MET)

Indications For Use:

Immunoassay for the qualitative detection of methamphetamine and 3,4-methylenedioxymethamphetamine (MDMA) at the cut-off of 500 ng/mL in urine to assist in screening of drugs of abuse samples at home and work place. For *In vitro* Diagnostic Use

This test provides only a preliminary analytical result and a more specific alternative chemical method must be used to obtain a confirmed analytical result and that GC/MS is the preferred confirmatory method.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Professional Use:___

Prescription Use:___ OR Over The Counter Use: _X__

(Per 21 CFR 801.109)

Division Sign-Off for Jean Cooper

(Optional Format 1-2-96)

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K023837

510(k) Number (if known): K023837

Device Name: LifeSign® Home Drug Test (Marijuana/Opiates/Cocaine/Ecstasy & MET)

Indications for Use:

Immunoassay for the qualitative detection of THC metabolite, opiates, cocaine metabolite, methamphetamine and 3,4-methylenedioxymethamphetamine in urine to assist in screening of drugs of abuse samples at home or work places. For *in vitro* Diagnostic Use. The detection cutoff concentrations are as follows:

THC	11-nor-Δ^9-THC-9-carboxylic acid	50 ng/ mL
OPI	Morphine	2000 ng/ mL
COC	Benzoylecgonine	300 ng/ mL
MET	D-Methamphetamine	500 ng/ mL
MDMA	3,4-methylenedioxymethamphetamine	500 ng/mL

This test provides only a preliminary analytical result and a more specific alternative chemical method must be used to obtain a confirmed analytical result and that GC/MS is the preferred confirmatory method.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Professional Use:____

Prescription Use:____ OR Over The Counter Use: _X__

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K023837