www.palveg.com

Certificaciones

PALVEG

COMISIÓN FEDERAL PARA LA PROTECCIÓN CONTRA RIESGOS SANITARIOS

CENTRO INTEGRAL DE SERVICIOS

Comprobante de Trámite

USO EXCLUSIVO COFEPRIS	FORMATO DE COFEPRIS-04
113300401B0982	Tipo de Trámite: **001**
20/09/2011	Homoclave del Trámite: **COFEPRIS-04-001-B**
16:35 hrs.	Subtipo: **SOLICITUD DE REGISTRO SANITARIO DE DISPOSITIVOS MÉDICOS**
	Modalidad: **B. PRODUCTOS DE IMPORTACIÓN (FABRICACIÓN EXTRANJERA)**

R.F.C. O C.U.R.P.:	**CPA 050518MY0**
NOMBRE O RAZÓN SOCIAL:	**COMERCIALIZADORA PALVEG, S.A. DE C.V.**
DOMICILIO:	**RAMON L VELARDE 39**
REPRESENTANTE LEGAL O RESPONSABLE SANITARIO :	**JOAN MANUEL PALMEROS VEGA**
NÚMERO DE INGRESO DE REFERENCIA :	
ANEXOS:	**OTROS: 1 CARPETA NEGRA**
REGISTRO SANITARIO:	
NÚM. DE BOLSA DE INF. CONFIDENCIAL:	
NÚM. FOLIO DE BOLSA DE INF. CONFIDENCIAL:	
MODO DE INGRESO Y ENTREGA:	**CENTRO INTEGRAL DE SERVICIOS VENTANILLA**

Secretaría de Salud
Comisión Federal para la Protección contra Riesgos Sanitarios
20 SET. 2011
RECIBIDO

Para obtener información sobre la disponibilidad de sus trámites usted podrá consultarnos en nuestra página www.cofepris.gob.mx en "Trámites Disponibles" o bien comunicarse al Centro de Atención Telefónica al número: **01 800 033 5050**.

Si la resolución de su trámite se encuentra disponible podrá recogerla contra entrega de este comprobante de trámite original en el Centro Integral de Servicios, donde permanecerán disponibles durante 30 días naturales y solo será entregada al representante legal, responsable sanitario o personas autorizadas notificadas ante ésta Comisión Federal previa presentación de identificación oficial.

The State of Wisconsin

Office of the
Secretary of State

APOSTILLE

(Convention de La Haye du 5 Octobre 1961)

1. Country: United States of America
2. This public document has been signed by Suzanne M. Brandon
3. acting in the capacity of Notary Public, State of Wisconsin
4. bears the seal/stamp of Notary Public, State of Wisconsin.

CERTIFIED for Mexico

5. at Madison, Wisconsin
6. June 2, 2011
7. by the Secretary of State of Wisconsin
8. No. 207312
9. Seal/stamp:

10. Signature

Douglas La Follette

DOUGLAS LA FOLLETTE
Secretary of State

This certificate only confirms the authority of the person named in Number 2. It does not mean that the contents of the attached document are correct, or that the Secretary of State approves of the contents.

Noble Medical, Inc.

19525 Janacek Court, Brookfield, WI 530458 Tel (262) 432-9308 Fax (262) 784-1246

Date: May 31, 2011

To whom it may concern:

LETTER OF AUTHORIZATION

Hereby the company NOBLE MEDICAL, Inc. located 19525 Janacek Court Ste 104, Brookfield, WI 53045, USA, authorizes COMERCIALIZADORA PALVEG, S.A. de C.V. to register in Mexico the medical device (in vitro diagnostic test) "Noble Medical Split-Specimen Cup" manufactured by Biosite, Inc. doing business as Innovacon, Inc., located in 9975 Summers Ridge Road, San Diego, Ca 92121,USA, with manufacturing facility at Abon Biopharm (Hangzhou) Co, Ltd, 198 12th Street East, Hangzhou Economic, & Technological Development Area, Hangzhou, Zhejiang, P.R. China, 310018.

To carry out this mandate, we authorize COMERCIALIZADORA PALVEG, S.A. DE C.V.:

- To submit documents;
- To sign the corresponding documents including application forms and any other normative documents;
- To receive any necessary documents;
- To receive the registration certificate.
- To take all necessary actions to register and sell this product.

Sincerely,

Managing Director
Noble Medical, Inc

Fecha: Mayo 31, 2011

A quien corresponda:

CARTA DE AUTORIZACION

Por este medio, la compañía NOBLE MEDICAL, Inc. ubicada en 19525 Janacek Court Ste 104, Brookfield, WI 53045, EUA, autoriza a COMERCIALIZADORA PALVEG, S.A. de C.V. para que registre en México el dispositivo médico (agente de diagnóstico in vitro) "Noble Medical Split-Specimen Cup" / "Prueba de Detección Multidrogas en Un Solo Paso en Panel Integrado en Vaso (Orina) Noble Medical", manufacturado por Biosite, Inc. quien hace negocios bajo el nombre de Innovacon, Inc., ubicada en 9975 Summers Ridge Road, San Diego, Ca 92121, EUA, con instalaciones de fabricación en Abon Biopharm (Hangzhou) Co., Ltd, 198 12th Street East Hangzhou Economic, & Technological Development Area, Hangzhou, Zhejiang, República Popular de CHINA, 310018.

Para llevar a cabo este mandato, autorizamos a COMERCIALIZADORA PALVEG, S.A. de C.V.:

- Para presentar documentos;
- Firmar los documentos correspondientes incluyendo solicitudes y cualquier otro documento normativo;
- Recibir cualquier documento necesario;
- Recibir el certificado de registro;
- Tomar todas las acciones necesarias para registrar y vender este producto.

Atentamente,

Director Ejecutivo
Noble Medical, Inc.

State of Wisconsin, County of Waukesha, this document was signed before me on May 31, 2011 by Andrew Falci.
Notary: Suzanne M. Brandon
Exp: 3/24/13

SUZANNE M BRANDON
Notary Public
State of Wisconsin

My Commission Expires
March 24, 2013

LA SIGUIENTE RAZON ES UNA CERTIFICACIÓN **SIN MAS ALCANCES QUE EL COTEJO DE ESTA COPIA CON EL ORIGINAL EXHIBIDO,** CON FUNDAMENTO EN LOS ARTÍCULOS NOVENTA Y SIETE FRACCIÓN PRIMERA Y CIENTO SESENTA DE LA LEY DEL NOTARIADO PARA EL DISTRITO FEDERAL EN VIGOR. ----------

YO, EL LICENCIADO ERIK NAMUR CAMPESINO, TITULAR DE LA NOTARÍA NÚMERO NOVENTA Y CUATRO DEL DISTRITO FEDERAL:----------

----------**C E R T I F I C O**----------

QUE LA PRESENTE COPIA FOTOSTÁTICA, ES UNA REPRODUCCIÓN FIEL Y EXACTA DEL ORIGINAL QUE TUVE A LA VISTA CON EL QUE LA COTEJE, DOCUMENTO CONSTANTE DE **DOS** FOJAS IMPRESAS; A DICHO COTEJO LE CORRESPONDIO EL ASIENTO **NÚMERO VEINTE MIL CIENTO DIECISÉIS,** BAJO LA LETRA **"C"**, DE ESTA FECHA, DEL LIBRO DE REGISTRO DE COTEJOS NÚMERO **DIECIOCHO** DE LA NOTARÍA A MI CARGO.- DOY FE.- MÉXICO, DISTRITO FEDERAL, A **DIECISIETE DE AGOSTO DEL AÑO DOS MIL ONCE**.----------

AOB/ygm*

LIC. ERIK NAMUR CAMPESINO
ESTADOS UNIDOS MEXICANOS
NOTARIA 94 DISTRITO FEDERAL, MEXICO

COLEGIO DE NOTARIOS DEL DISTRITO FEDERAL

State of California

SECRETARY OF STATE

This Apostille only certifies the authenticity of the signature and the title of the public official who has signed the public document, and, where appropriate, the identity of the seal or stamp which the public document bears. This Apostille does not certify the authenticity of the underlying document for which it was issued. This Apostille is not valid for use anywhere within the United States of America, its territories or possessions. To verify the issuance of this Apostille, go to www.sos.ca.gov/business/notary/apostille-search/

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. *Country: United States of America*
   This public document
2. *has been signed by Lisa R. Morgan*
3. *acting in the capacity of Notary Public, State of California*
4. *bears the seal/stamp of Lisa R. Morgan, Notary Public, State of California*

CERTIFIED

5. *At Sacramento, California*
6. *the 14th day of June 2011*
7. *by Deputy Secretary of State, State of California*
8. *No. 974163*
9. *Seal/Stamp:*

10. *Signature*

Jena Bowen
Secretary of State

BY Karen L. Cates

NP-24 A (REV. 1-07)

OSP 07 104060

9975 Summers Ridge Road
San Diego, CA 92121, USA

To Whom It May Concern:

As a responsible official of Alere SD Inc., dba Biosite Inc., dba Innovacon Inc. I, Lisa Chicorka, hereby certify that the attached FDA 510(k) Clearance Letter and Summary is a true and correct copy.

Signature

Lisa Chicorka
Sr. Regulatory Specialist

Typed Name and Title

Attachment(s):

FDA 510(k) Clearance Letter and Summary

State of California
County of San Diego

Subscribed and sworn to (or affirmed) before me on this 01 day of June, 20 11, by Lisa Chicorka,
proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

LISA R. MORGAN
Commission # 1910934
Notary Public - California
San Diego County
My Comm. Expires Oct 29, 2014

(Seal)

Signature

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 13 2006

Edward Tung, Ph.D.
INNOVACON Laboratories, Inc.
4106 Sorrento Valley Boulevard
San Diego, California 92121

Re: k061718
Trade/Device Name: Innovacon Spectrum II Test Card
Innovacon Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup)
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ, DIS, JXM, LDJ, DIO, DJR, DJC, DJG, LFG, LCM, JXN
Dated: October 20, 2006
Received: October 23, 2006

Dear Dr. Tung:

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 (240) 276-0484. 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/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

SÍNTEXTO

10. INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Innovacon Spectrum II Test Card
Innovacon Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup)

Indications for Use:

The Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) are rapid chromatographic immunoassays for the qualitative and simultaneous detection of Marijuana, Cocaine, Methylenedioxymethamphetamine, Amphetamine, Morphine, Opiates, Methadone, Methamphetamine, Phencyclidine, Benzodiazepine, Oxycodone, Propoxyphene, Tricyclic Antidepressants, Buprenorphine and Barbiturate in human urine at the cutoff concentrations of:

1,000 ng/mL or 300 ng/mL for Amphetamine,
300 ng/mL for Barbiturate,
300 ng/mL for Benzodiazepines,
300 ng/mL or 150 ng/mL for Cocaine,
50 ng/mL for Marijuana,
300 ng/mL for Methadone,
500 ng/mL or 1,000 ng/mL for Methamphetamine,
500 ng/mL for Methylenedioxymethamphetamine,
300 ng/mL for Morphine,
2,000 ng/mL for Opiates,
100 ng/mL for Oxycodone,
25 ng/mL for Phencyclidine,
300 ng/mL for Propoxyphene,
10 ng/mL for Buprenorphine, and
1,000 ng/mL for Tricyclic Antidepressants.

Configurations of the Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with Integarted Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) can consist of any combination of the above listed drug analytes. They are intended for healthcare professionals including professionals at point-of-care sites.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Prescription Use ... X ... AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K061718

SIN TEXTO

NOV 13 2006

510(k) SUMMARY

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

The Assigned 510(k) number is K061718.

Submitter:

INNOVACON Laboratories, Inc.
4106 Sorrento Valley Boulevard
San Diego, California 92121

Tel.: 858-535-2030
Fax: 858-535-2038

Date:

June 16, 2006

Contact Person:

Edward Tung, Ph.D.

Product Names:

Innovacon® Spectrum II Test Card
Innovacon® Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup)

Common Name:

Multi-drug Multi-line lateral flow immunochromatographic test for the simultaneous and qualitative detection of Amphetamine, Cocaine, Marijuana, Benzodiazepines, Tricyclic Antidepressants, Barbiturates, Morphine, Phencyclidine, Oxycodone, Propoxyphene, Methadone, Opiate, Methamphetamine, Buprenorphine and Methylenedioxymethamphetamine in urine.

SIN TEXTO

Regulation Name:

Amphetamine, Cocaine, Marijuana, Benzodiazepines, Tricyclic Antidepressants, Barbiturates, Morphine, Phencyclidine, Oxycodone, Propoxyphene, Methadone, Opiate, Methylenedioxymethamphetamine, Buprenorphine and Methamphetamine test systems.

Product Code:

LDJ, DIO, DJC, DKZ, DJG, LCM, JXM, DJR, DIS, LFG, LAF, JXN

Classification Number:

21 CFR § 862.3870, 21 CFR § 862.3250, 21 CFR § 862.3610, 21 CFR § 862.3100, 21 CFR § 862.3650, 21 CFR § 862.3170, 21 CFR § 862.3620, 21 CFR § 862.3150, 21 CFR § 862.3910, 21 CFR § 862.3700

Device Classification:

The Amphetamine, Cocaine, Marijuana, Benzodiazepines, Tricyclic Antidepressants, Barbiturates, Morphine, Phencyclidine, Oxycodone, Propoxyphene, Methadone, Opiate, Methylenedioxymethamphetamine, Buprenorphine and Methamphetamine test systems have been classified as Class II devices with moderate complexity.

The Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) are similar to other FDA-cleared devices for the qualitative and simultaneous detection of Amphetamine, Cocaine, Marijuana, Benzodiazepines, Tricyclic Antidepressants, Barbiturates, Morphine, Phencyclidine, Oxycodone, Propoxyphene, Methadone, Opiate, Methylenedioxymethamphetamine, Buprenorphine and Methamphetamine in human urine.

Intended Use:

The Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) are rapid chromatographic immunoassays for the qualitative and simultaneous detection of Marijuana, Cocaine, Methylenedioxymethamphetamine, Amphetamine, Morphine, Opiates, Methadone, Methamphetamine, Phencyclidine,

SIN TEXTO

Benzodiazepine, Oxycodone, Propoxyphene, Tricyclic Antidepressants, Buprenorphine and Barbiturate in human urine at the cutoff concentrations of:

1,000 ng/mL or 300 ng/mL for Amphetamine,
300 ng/mL for Barbiturate,
300 ng/mL for Benzodiazepines,
300 ng/mL or 150 ng/mL for Cocaine,
50 ng/mL for Marijuana,
300 ng/mL for Methadone,
500 ng/mL or 1,000 ng/mL for Methamphetamine,
500 ng/mL for Methylenedioxymethamphetamine,
300 ng/mL for Morphine,
2,000 ng/mL for Opiates,
100 ng/mL for Oxycodone,
25 ng/mL for Phencyclidine,
300 ng/mL for Propoxyphene,
10 ng/mL for Buprenorphine, and
1,000 ng/mL for Tricyclic Antidepressants.

Configurations of the Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) can consist of any combination of the above listed drug analytes. They are intended for healthcare professionals including professionals at point-of-care sites.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Description:

The Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) are competitive binding, lateral flow immunochromatographic assays for the qualitative and simultaneous detection of Marijuana, Cocaine, Methylenedioxymethamphetamine, Amphetamine, Morphine, Opiates, Methadone, Methamphetamine, Phencyclidine, Benzodiazepine, Oxycodone, Propoxyphene, Tricyclic Antidepressants, Buprenorphine and Barbiturate in human urine at the cutoff concentrations of:

1,000 ng/mL or 300 ng/mL for Amphetamine,
300 ng/mL for Barbiturate,
300 ng/mL for Benzodiazepines,
300 ng/mL or 150 ng/mL for Cocaine,
50 ng/mL for Marijuana,
300 ng/mL for Methadone,
500 ng/mL or 1,000 ng/mL for Methamphetamine,
500 ng/mL for Methylenedioxymethamphetamine,
300 ng/mL for Morphine,
2,000 ng/mL for Opiates,
100 ng/mL for Oxycodone,
25 ng/mL for Phencyclidine,
300 ng/mL for Propoxyphene,
10 ng/mL for Buprenorphine, and
1,000 ng/mL for Tricyclic Antidepressants.

These tests can be performed without the use of an instrument.

A positive urine specimen will not generate a colored-line for the specific drug tested in the designated test region. A negative urine specimen or a urine specimen containing of Marijuana, Cocaine, Methylenedioxymethamphetamine, Amphetamine, Morphine, Opiates, Methadone, Methamphetamine, Phencyclidine, Benzodiazepine, Oxycodone, Propoxyphene, Tricyclic Antidepressants, Buprenorphine and Barbiturate at the concentrations 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 color line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Unmodified ACON Devices:

The Innovacon® Spectrum II Test Card and Innovacon Spectrum II Test Card with with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) are a "modified" product format derived from the previously FDA-cleared ACON Spectrum Multi-drug Multi-line Drug Screen Test Card and 6 ACON Single DOA Tests. These seven legally marketed but unmodified devices and their 510(k) numbers under which they were previously cleared are listed in Table 1.

SIN TEXTO

Table 1. Unmodified ACON Devices with K Numbers and Product Codes.

Previously Cleared ACON Drug of Abuse Test	510(k) Number	Product Code
ACON Spectrum Multi-Drug Multi-Line Drug Screen Test Card and Test Card with Integrated Split E-Z Key Cup	K031759	LDJ DIO DKZ DJG LCM JXM DJR DJS LFG
ACON COC-150 One Step Cocaine Test Strip/Test Device	K032903	DIO
ACON mAMP-500 One Step Methamphetamine Test Strip/Test Device	K033299	LAF
ACON PPX One Step Propoxyphene Test Strip/Test Device	K040445	JXN
ACON AMP 300 One Step Amphetamine Test Strip/Test Device	K041822	DKZ
ACON OXY II One Step Oxycodone Test Strip/Test Device	K043507	DJG
ACON BUP One Step Buprenorphine Test Strip/Test Device	K060466	DJG

LA SIGUIENTE RAZON ES UNA CERTIFICACIÓN **SIN MAS ALCANCES QUE EL COTEJO DE ESTA COPIA CON EL ORIGINAL EXHIBIDO,** CON FUNDAMENTO EN LOS ARTÍCULOS NOVENTA Y SIETE FRACCIÓN PRIMERA Y CIENTO SESENTA DE LA LEY DEL NOTARIADO PARA EL DISTRITO FEDERAL EN VIGOR. ----------

YO, EL LICENCIADO ERIK NAMUR CAMPESINO, TITULAR DE LA NOTARÍA NÚMERO NOVENTA Y CUATRO DEL DISTRITO FEDERAL:----------

----------**C E R T I F I C O**----------

QUE LA PRESENTE COPIA FOTOSTÁTICA, ES UNA REPRODUCCIÓN FIEL Y EXACTA DEL ORIGINAL QUE TUVE A LA VISTA CON EL QUE LA COTEJE, DOCUMENTO CONSTANTE DE **DIEZ** FOJAS IMPRESAS; A DICHO COTEJO LE CORRESPONDIO EL ASIENTO **NÚMERO VEINTE MIL CIENTO DIECISÉIS,** BAJO LA LETRA **"A"**, DE ESTA FECHA, DEL LIBRO DE REGISTRO DE COTEJOS NÚMERO **DIECIOCHO** DE LA NOTARÍA A MI CARGO.- DOY FE.- MÉXICO, DISTRITO FEDERAL, A **DIECISIETE DE AGOSTO DEL AÑO DOS MIL ONCE**.----------

AOB/ygm*

LIC. ERIK NAMUR CAMPESINO
ESTADOS UNIDOS MEXICANOS
NOTARIA 94 DISTRITO FEDERAL, MEXICO

COLEGIO DE NOTARIOS DEL DISTRITO FEDERAL

State of California

SECRETARY OF STATE

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APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. *Country: United States of America*
   This public document
2. *has been signed by Lisa R. Morgan*
3. *acting in the capacity of Notary Public, State of California*
4. *bears the seal/stamp of Lisa R. Morgan, Notary Public, State of California*

CERTIFIED

5. *At Sacramento, California*
6. *the 14th day of June 2011*
7. *by Deputy Secretary of State, State of California*
8. *No. 974163*
9. *Seal/Stamp:*

10. *Signature*

Jena Bowen
Secretary of State

BY Karen L. Cates

NP-24 A (REV. 1-07)

OSP 07 104060

9975 Summers Ridge Road
San Diego, CA 92121, USA

To Whom It May Concern:

As a responsible official of Alere SD Inc., dba Biosite Inc., dba Innovacon Inc., I, Lisa Chicorka, hereby certify that the attached FDA 510(k) Clearance Letter and Summary is a true and correct copy.

Signature

Lisa Chicorka
Sr. Regulatory Specialist

Typed Name and Title

Attachment(s):

FDA 510(k) Clearance Letter and Summary

State of California
County of San Diego

Subscribed and sworn to (or affirmed) before me on this 01 day of June, 20 11, by Lisa Chicorka,
proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

LISA R. MORGAN
Commission # 1910934
Notary Public - California
San Diego County
My Comm. Expires Oct 29, 2014

(Seal)

Signature

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 13 2006

Edward Tung, Ph.D.
INNOVACON Laboratories, Inc.
4106 Sorrento Valley Boulevard
San Diego, California 92121

Re: k061718
Trade/Device Name: Innovacon Spectrum II Test Card
Innovacon Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup)
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ, DIS, JXM, LDJ, DIO, DJR, DJC, DJG, LFG, LCM, JXN
Dated: October 20, 2006
Received: October 23, 2006

Dear Dr. Tung:

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).

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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 (240) 276-0484. 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/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

10. INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Innovacon Spectrum II Test Card
Innovacon Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup)

Indications for Use:

The Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) are rapid chromatographic immunoassays for the qualitative and simultaneous detection of Marijuana, Cocaine, Methylenedioxymethamphetamine, Amphetamine, Morphine, Opiates, Methadone, Methamphetamine, Phencyclidine, Benzodiazepine, Oxycodone, Propoxyphene, Tricyclic Antidepressants, Buprenorphine and Barbiturate in human urine at the cutoff concentrations of:

1,000 ng/mL or 300 ng/mL for Amphetamine,
300 ng/mL for Barbiturate,
300 ng/mL for Benzodiazepines,
300 ng/mL or 150 ng/mL for Cocaine,
50 ng/mL for Marijuana,
300 ng/mL for Methadone,
500 ng/mL or 1,000 ng/mL for Methamphetamine,
500 ng/mL for Methylenedioxymethamphetamine,
300 ng/mL for Morphine,
2,000 ng/mL for Opiates,
100 ng/mL for Oxycodone,
25 ng/mL for Phencyclidine,
300 ng/mL for Propoxyphene,
10 ng/mL for Buprenorphine, and
1,000 ng/mL for Tricyclic Antidepressants.

Configurations of the Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with Integarted Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) can consist of any combination of the above listed drug analytes. They are intended for healthcare professionals including professionals at point-of-care sites.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Prescription Use ... X ... (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K061718

NOV 13 2006

510(k) SUMMARY

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

The Assigned 510(k) number is K061718.

Submitter:

INNOVACON Laboratories, Inc.
4106 Sorrento Valley Boulevard
San Diego, California 92121

Tel.: 858-535-2030
Fax: 858-535-2038

Date:

June 16, 2006

Contact Person:

Edward Tung, Ph.D.

Product Names:

Innovacon® Spectrum II Test Card
Innovacon® Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup)

Common Name:

Multi-drug Multi-line lateral flow immunochromatographic test for the simultaneous and qualitative detection of Amphetamine, Cocaine, Marijuana, Benzodiazepines, Tricyclic Antidepressants, Barbiturates, Morphine, Phencyclidine, Oxycodone, Propoxyphene, Methadone, Opiate, Methamphetamine, Buprenorphine and Methylenedioxymethamphetamine in urine.

Regulation Name:

Amphetamine, Cocaine, Marijuana, Benzodiazepines, Tricyclic Antidepressants, Barbiturates, Morphine, Phencyclidine, Oxycodone, Propoxyphene, Methadone, Opiate, Methylenedioxymethamphetamine, Buprenorphine and Methamphetamine test systems,

Product Code:

LDJ, DIO, DJC, DKZ, DJG, LCM, JXM, DJR, DIS, LFG, LAF, JXN

Classification Number:

21 CFR § 862.3870, 21 CFR § 862.3250, 21 CFR § 862.3610, 21 CFR § 862.3100, 21 CFR § 862.3650, 21 CFR § 862.3170, 21 CFR § 862.3620, 21 CFR § 862.3150, 21 CFR § 862.3910, 21 CFR § 862.3700

Device Classification:

The Amphetamine, Cocaine, Marijuana, Benzodiazepines, Tricyclic Antidepressants, Barbiturates, Morphine, Phencyclidine, Oxycodone, Propoxyphene, Methadone, Opiate, Methylenedioxymethamphetamine, Buprenorphine and Methamphetamine test systems have been classified as Class II devices with moderate complexity.

The Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) are similar to other FDA-cleared devices for the qualitative and simultaneous detection of Amphetamine, Cocaine, Marijuana, Benzodiazepines, Tricyclic Antidepressants, Barbiturates, Morphine, Phencyclidine, Oxycodone, Propoxyphene, Methadone, Opiate, Methylenedioxymethamphetamine, Buprenorphine and Methamphetamine in human urine.

Intended Use:

The Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) are rapid chromatographic immunoassays for the qualitative and simultaneous detection of Marijuana, Cocaine, Methylenedioxymethamphetamine, Amphetamine, Morphine, Opiates, Methadone, Methamphetamine, Phencyclidine,

Benzodiazepine, Oxycodone, Propoxyphene, Tricyclic Antidepressants, Buprenorphine and Barbiturate in human urine at the cutoff concentrations of:

1,000 ng/mL or 300 ng/mL for Amphetamine,
300 ng/mL for Barbiturate,
300 ng/mL for Benzodiazepines,
300 ng/mL or 150 ng/mL for Cocaine,
50 ng/mL for Marijuana,
300 ng/mL for Methadone,
500 ng/mL or 1,000 ng/mL for Methamphetamine,
500 ng/mL for Methylenedioxymethamphetamine,
300 ng/mL for Morphine,
2,000 ng/mL for Opiates,
100 ng/mL for Oxycodone,
25 ng/mL for Phencyclidine,
300 ng/mL for Propoxyphene,
10 ng/mL for Buprenorphine, and
1,000 ng/mL for Tricyclic Antidepressants.

Configurations of the Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) can consist of any combination of the above listed drug analytes. They are intended for healthcare professionals including professionals at point-of-care sites.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Description:

The Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) are competitive binding, lateral flow immunochromatographic assays for the qualitative and simultaneous detection of Marijuana, Cocaine, Methylenedioxymethamphetamine, Amphetamine, Morphine, Opiates, Methadone, Methamphetamine, Phencyclidine, Benzodiazepine, Oxycodone, Propoxyphene, Tricyclic Antidepressants, Buprenorphine and Barbiturate in human urine at the cutoff concentrations of:

1,000 ng/mL or 300 ng/mL for Amphetamine,
300 ng/mL for Barbiturate,
300 ng/mL for Benzodiazepines,
300 ng/mL or 150 ng/mL for Cocaine,
50 ng/mL for Marijuana,
300 ng/mL for Methadone,
500 ng/mL or 1,000 ng/mL for Methamphetamine,
500 ng/mL for Methylenedioxymethamphetamine,
300 ng/mL for Morphine,
2,000 ng/mL for Opiates,
100 ng/mL for Oxycodone,
25 ng/mL for Phencyclidine,
300 ng/mL for Propoxyphene,
10 ng/mL for Buprenorphine, and
1,000 ng/mL for Tricyclic Antidepressants.

These tests can be performed without the use of an instrument.

A positive urine specimen will not generate a colored-line for the specific drug tested in the designated test region. A negative urine specimen or a urine specimen containing of Marijuana, Cocaine, Methylenedioxymethamphetamine, Amphetamine, Morphine, Opiates, Methadone, Methamphetamine, Phencyclidine, Benzodiazepine, Oxycodone, Propoxyphene, Tricyclic Antidepressants, Buprenorphine and Barbiturate at the concentrations 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 color line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Unmodified ACON Devices:

The Innovacon® Spectrum II Test Card and Innovacon Spectrum II Test Card with with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) are a "modified" product format derived from the previously FDA-cleared ACON Spectrum Multi-drug Multi-line Drug Screen Test Card and 6 ACON Single DOA Tests. These seven legally marketed but unmodified devices and their 510(k) numbers under which they were previously cleared are listed in Table 1.

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Table 1. Unmodified ACON Devices with K Numbers and Product Codes.

Previously Cleared ACON Drug of Abuse Test	510(k) Number	Product Code
ACON Spectrum Multi-Drug Multi-Line Drug Screen Test Card and Test Card with Integrated Split E-Z Key Cup	K031759	LDJ DIO DKZ DJG LCM JXM DJR DIS LFG
ACON COC-150 One Step Cocaine Test Strip/Test Device	K032903	DIO
ACON mAMP-500 One Step Methamphetamine Test Strip/Test Device	K033299	LAF
ACON PPX One Step Propoxyphene Test Strip/Test Device	K040445	JXN
ACON AMP 300 One Step Amphetamine Test Strip/Test Device	K041822	DKZ
ACON OXY II One Step Oxycodone Test Strip/Test Device	K043507	DJG
ACON BUP One Step Buprenorphine Test Strip/Test Device	K060466	DJG

LA SIGUIENTE RAZON ES UNA CERTIFICACIÓN **SIN MAS ALCANCES QUE EL COTEJO DE ESTA COPIA CON EL ORIGINAL EXHIBIDO,** CON FUNDAMENTO EN LOS ARTÍCULOS NOVENTA Y SIETE FRACCIÓN PRIMERA Y CIENTO SESENTA DE LA LEY DEL NOTARIADO PARA EL DISTRITO FEDERAL EN VIGOR. ----------

YO, EL LICENCIADO ERIK NAMUR CAMPESINO, TITULAR DE LA NOTARÍA NÚMERO NOVENTA Y CUATRO DEL DISTRITO FEDERAL:----------

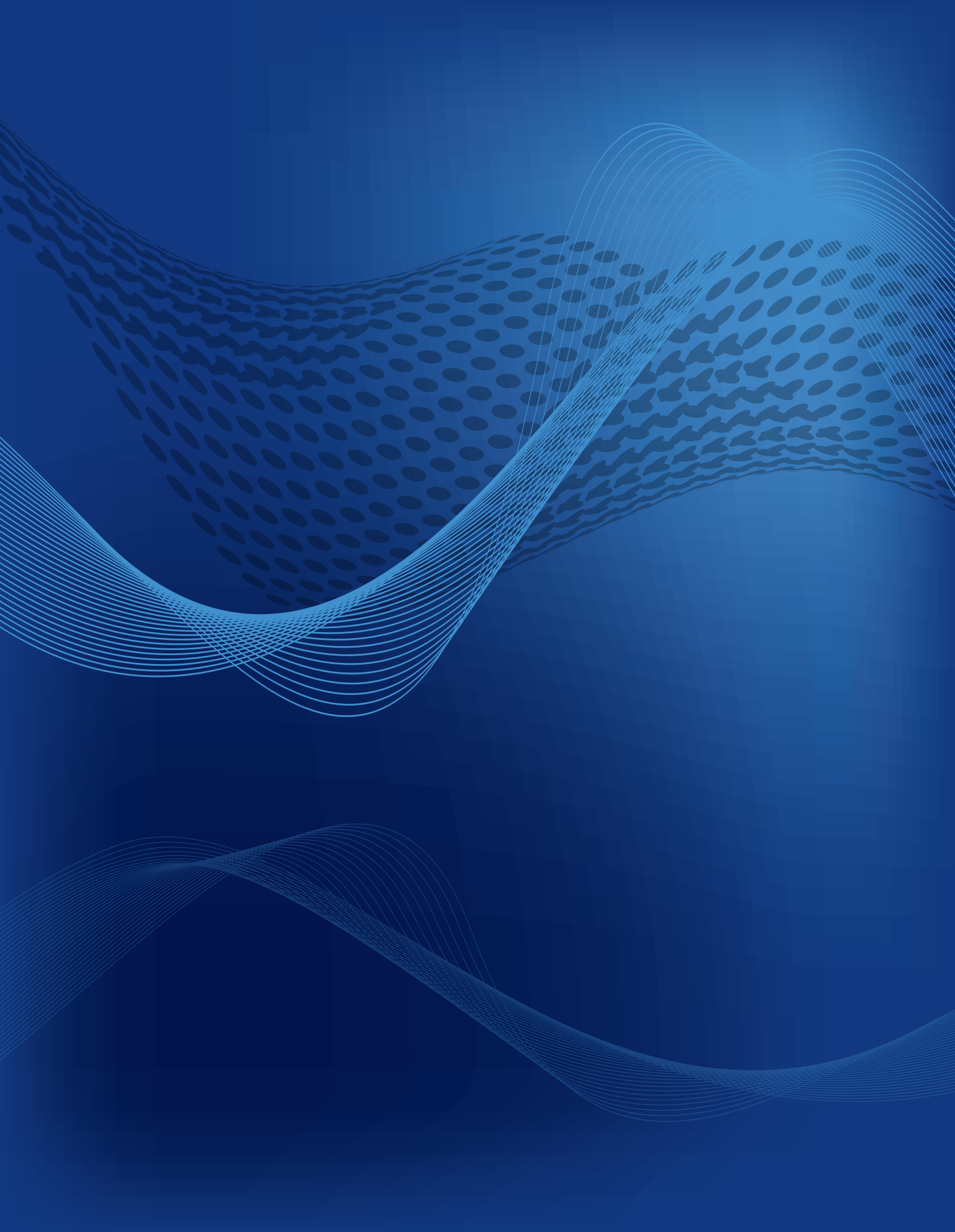
----------**C E R T I F I C O**----------

QUE LA PRESENTE COPIA FOTOSTÁTICA, ES UNA REPRODUCCIÓN FIEL Y EXACTA DEL ORIGINAL QUE TUVE A LA VISTA CON EL QUE LA COTEJE, DOCUMENTO CONSTANTE DE **DIEZ** FOJAS IMPRESAS; A DICHO COTEJO LE CORRESPONDIO EL ASIENTO **NÚMERO VEINTE MIL CIENTO DIECISÉIS,** BAJO LA LETRA **"A"**, DE ESTA FECHA, DEL LIBRO DE REGISTRO DE COTEJOS NÚMERO **DIECIOCHO** DE LA NOTARÍA A MI CARGO.- DOY FE.- MÉXICO, DISTRITO FEDERAL, A **DIECISIETE DE AGOSTO DEL AÑO DOS MIL ONCE**.----------

AOB/ygm*

LIC. ERIK NAMUR CAMPESINO
ESTADOS UNIDOS MEXICANOS
NOTARIA 94 DISTRITO FEDERAL, MEXICO

COLEGIO DE NOTARIOS DEL DISTRITO FEDERAL



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