

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 2006

Innovision A/S
c/o Mr. Richard O. Wood
The Wood Burditt Group
1025 W. Everett Rd, Suite 100
Lake Forest, IL 60045

Re: K051907

Trade Name: Innocor
Regulation Number: 21 CFR 870.1425
Regulation Name: Diagnostic Programmable Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: July 13, 2005
Received: July 14, 2005

Dear Mr. Wood:

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 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.

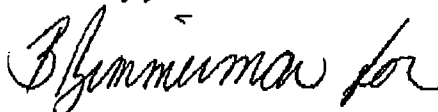
Page 2 – Mr. Richard O. Wood

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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051907

Device Name: Innocor

Indications For Use: Innocor is indicated for the determination of a number of hemodynamic parameters.

Cardiac Output (CO) is the principal measured parameter. Utilizing inert gas rebreathing, Innocor measures the relative levels of two inhaled gases of differing blood solubility over approximately 3-4 respirations and calculates pulmonary blood flow (PBF). In the absence of a significant intrapulmonary shunt (arterial oxygen saturation \leq 95% as measured by a pulse oximeter incorporated in the Innocor), PBF is equal to CO.

As an optional accessory, Innocor includes a noninvasive Blood Pressure (NIBP) monitoring system. This option provides systolic, diastolic and mean arterial pressures.

With the NIBP option, Innocor provides values for the following measured and calculated hemodynamic parameters:

- Cardiac Output
- Arterial Oxygen Saturation
- Heart Rate
- Stroke Volume
- Lung Volume
- Cardiac Index
- Stroke Index
- Blood Pressures (Systolic, Diastolic, Mean Arterial)
- Systemic Vascular Resistance
- Systemic Vascular Resistance Index

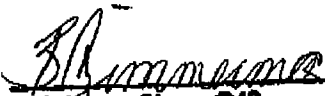
• Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K051907

Page 1 of 1



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 7 2007

Innovision A/S
c/o Mr. Richard O. Wood
Sponsor Representative
The Wood Burditt Group LLC
1025 Everett Road, Suite 100
Lake Forest, IL 60045

Re: K071911
Trade Name: Innocor, Models INN00400 and INN00500
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: August 29, 2007
Received: September 5, 2007

Dear Mr. Wood:

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.

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Page 2 - Mr. Richard O. Wood

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K071911

Device Name: Cardiopulmonary Exercise Testing Option to Innocor

Indications for Use:

A cardiopulmonary exercise testing option is available for Innocor. This option provides breath-by-breath measurements of flow, oxygen uptake and carbon dioxide production. It is intended to measure oxygen uptake (metabolic rate) and related parameters to objectively and non-invasively assess cardiac and pulmonary function at rest and during exercise. With the cardiopulmonary exercise testing option, Innocor provides values for:

Main metabolic parameters:

- Oxygen uptake
- Carbon dioxide excretion
- Expiratory minute ventilation

Calculated/derived parameters:

- Oxygen uptake per kg
- Respiratory exchange ratio
- Alveolar ventilation
- Anatomical dead space (Fowler dead space)
- Tidal volume
- Respiratory rate
- End-tidal concentration of oxygen
- End-tidal concentration of carbon dioxide
- Expiratory quotient / ventilatory equivalent for oxygen
- Expiratory quotient / ventilatory equivalent for carbon dioxide

And the following calculated parameters after an incremental exercise test:

- Anaerobic threshold
- Respiratory compensation
- Rest values
- Values at AT point
- Values at max exercise

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

B. A. [Signature]
(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K071911



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

The Wood Burditt Group LLC.
c/o Mr. H. Carl Jenkins
Regulatory Affairs Counsel
10 E. Scranton Ave., Suite 201
Lake Bluff, IL 60044

FEB 23 2009

Re: K083879
Spirometry Option for Innocor
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK, BZG and BZL
Dated: December 12, 2008
Received: December 29, 2008

Dear Mr. Jenkins:

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.

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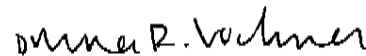
Page 2 - Mr. H. Carl Jenkins


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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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

Spirometry Option for Innocor

Indications for Use

510(k) Number (if known): K083879

Device Name: Spirometry Option for Innocor

Indications for Use:

The Spirometry Option for Innocor is intended to be used as a diagnostic spirometer, used in pulmonary function testing, to measure the flow of gas moving into and out of a patient's lungs.

In order to produce data regarding the maximum performance with respect to tidal volume and ventilation, the specific parameters measured by the Innocor Spirometry Option are:

Abbreviation	Name	Unit
FEV ₁	Forced expiratory volume in one second	L [BTPS]
FVC	Forced vital capacity	L [BTPS]
FEV ₁ %	FEV ₁ / FVC	%
PEF	Peak expiratory flow	l/sec [BTPS]
MEF 75*	Maximum instantaneous forced expiratory flow where 75% of the FVC remains to be expired	l/sec [BTPS]
MEF 50*	Maximum instantaneous forced expiratory flow where 50% of the FVC remains to be expired	l/sec [BTPS]
MEF 25*	Maximum instantaneous forced expiratory flow where 25% of the FVC remains to be expired	l/sec [BTPS]
FET	Forced expiratory time	Sec
MVV	Maximum voluntary ventilation	L/min [BTPS]

*MEF 75 is equal to FEF 25 (maximal instantaneous forced expiratory flow where 25% of the FVC has been expired); MEF 50 is equal to FEF 50; MEF 25 is equal to FEF 75.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Danna R. Cochran
(Division Sign-Off)
Division of Cardiovascular Devices



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

NOV - 1 2011

Innovision A/V
Regulatory Counsel
C/O Mr. H. Carl Jenkins
The Wood Burditt Group LLC
10 E. Scranton Avenue, Suite 201
Lake Bluff, Illinois 60044

Re: K102047

Trade/Device Name: LCI Option for Innocor
Regulation Number: 21 CFR 868.1880
Regulation Name: Pulmonary-Function Data Calculator
Regulatory Class: II
Product Code: BZC
Dated: April 5, 2011
Received: April 6, 2011

Dear Mr. Jenkins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 – Mr. Jenkins

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

LCI Option for Innocor

Indications for Use

510(k) Number (if known): _____

Device Name: LCI Option for Innocor

Indications for Use:

The LCI Option for Innocor is intended to measure the Lung Clearance Index (LCI), which is the cumulative expired volume required to clear an inert gas from the lungs during normal breathing in a multiple-breath washout (MBW) test divided by the Functional Residual Capacity (FRC).

The specific parameters measured by the Innocor LCI Option include:

Abbreviation	Name	Unit
LCI	Lung Clearance Index	(none)
FRC	Functional Residual Capacity	L [BTPS]

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices