Date of Summary	12/12/2008
Submitter/Contact Person	H. Carl Jenkins FEB 23 2009 The **Wood Burditt** Group 1025 W. Everett Rd., Suite 100 Lake Forest, IL 60045 (ph) (847) 234-7500 x 205 (fax) (847) 574-0728 (email) hcjenkins@woodburditt.com
Applicant	Innovision A/S Lindvedvej 75 DK-5260 Odense S Denmark Phone: +45 65 95 91 00 Fax: +45 65 95 78 00 info@innovision.dk www.innovision.dk
Device Name	Spirometry Option to Innocor
Common Name	Diagnostic Spirometer
Classification	***[Hemodynamic Measurements—Already Cleared K051907]*** Computer, diagnostic, programmable Regulation Number: 21 CFR §870.1425 Product Code: DQK Panel Code: Cardiovascular Device Class: IIa ***[Cardiopulmonary Exercise Testing Option – Already Cleared K071911]*** Oxygen uptake computer Regulation Number: 21 CFR §868.1730 Product Code: BZL Panel Code: Anesthesiology Device Class: IIa

	[Spirometry Option] Diagnostic spirometer Regulation Number: 21 CFR §868.1840 Product Code: BZG Panel Code: Anesthesiology Device Class: II
Legally Marketed Predicate Devices	The Spirometry Option for Innocor is substantially equivalent in respect to the intended use, design and method of operation to: *Predicate Device No. 1* Name: Innocor 510(k) number: K051907 Manufacturer: Innovision A/S, Denmark *Predicate Device No. 2* Name: Cardiopulmonary Exercise Testing Option 510(k) number: K071911 Manufacturer: Innovision A/S, Denmark *Predicate Device No. 3* Name: Spirobank G 510(k) number: K072979 Manufacturer: MIR Medical International Research
Device Description	**Innocor** is a compact point-of-care device intended to be used for non-invasive measurement of a) cardiac output (CO) and other hemodynamic parameters utilizing inert gas rebreathing (IGR) technology, and b) metabolic parameters including oxygen uptake by means of a breath-by-breath gas exchange method. **The Cardiopulmonary Exercise Testing Option to Innocor**

	provides measurements of gas exchange parameters including oxygen uptake (VO_2), carbon dioxide excretion (VCO_2), ventilation (V_E) and end-tidal gas concentrations plus a number of derived parameters. These parameters are determined by simultaneous measurements of the respiratory flow and gas concentrations when breathing ambient air. The respiratory flow is measured by means of a differential pressure type flowmeter (pneumotachometer) placed between the respiratory valve unit and the patient. The gas exchange calculations are carried out online for each breath between the rebreathing tests, providing the opportunity to perform an incremental exercise test on a bicycle ergometer or treadmill and measure the progress of cardiac function, pulmonary function and gas exchange at the same time. Spirometry is a physiological test that measures how an individual inhales or exhales volumes of air as a function of time. Spirometry is recognized as a valuable screening test of general respiratory health. **The Spirometry Option for Innocor** measures the subset of spirometric variables of a patient during a forced expiration testing procedure. These measured variables include FEV_1 (forced expiratory volume in 1 second), FVC (forced vital capacity), FEV_1%, PEF (peak expiratory flow), MEF 75 (Maximal instantaneous forced expiratory flow where 75% of the FVC remains to be expired), MEF 50, MEF 25, FET (Forced expiratory time) and MVV (Maximum voluntary ventilation). These parameters are determined by measurements of the respiratory flow when breathing ambient air during a spirometry test of a patient (tidal breathing followed by a full inspiration and then finally a maximal forced expiration). The respiratory flow is measured by means of a pneumotachometer.

<table>
<tr><td></td><td>The Spirometry Option for Innocor, used in conjunction with the entire Innocor system, provides health care providers with a set of valuable diagnostic tools.</td></tr>
<tr><td>Intended Use and Indications</td><td>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 in 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:

<table>
<tr><th>Abbreviation</th><th>Name</th><th>Unit</th></tr>
<tr><td>FEV_1</td><td>Forced expiratory volume in one second</td><td>L [BTPS]</td></tr>
<tr><td>FVC</td><td>Forced vital capacity</td><td>L [BTPS]</td></tr>
<tr><td>$FEV_1\%$</td><td>FEV_1 / FVC</td><td>%</td></tr>
<tr><td>PEF</td><td>Peak expiratory flow</td><td>l/sec [BTPS]</td></tr>
<tr><td>MEF 75*</td><td>Maximum instantaneous forced expiratory flow where 75% of the FVC remains to be expired</td><td>l/sec [BTPS]</td></tr>
<tr><td>MEF 50*</td><td>Maximum instantaneous forced expiratory flow where 50% of the FVC remains to be expired</td><td>l/sec [BTPS]</td></tr>
<tr><td>MEF 25*</td><td>Maximum instantaneous forced expiratory flow where 25% of the FVC remains to be expired</td><td>l/sec [BTPS]</td></tr>
<tr><td>FET</td><td>Forced expiratory time</td><td>Sec</td></tr>
<tr><td>MVV</td><td>Maximum voluntary ventilation</td><td>L/min [BTPS]</td></tr>
</table>
</td></tr>
</table>

	**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 25is equal to FEF 75.*
Performance Testing	The Spirometry Option for Innocor has been evaluated against the "Standardisation of Spirometry" document in the series "ATS/ERS Task Force: Standardisation of Lung Function Testing," issued by The American Thoracic Society (ATS) and the European Respiratory Society (ERS). Performance data demonstrates that the hardware and software meet the ATS/ERS standards, and the Spirometry Option for Innocor is accordingly substantially equivalent to legally marketed predicate diagnostic spirometers.

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.

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.

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" (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

Indications for Use

510(k) Number (if known): K083879

Device Name: Spirometry Option for Innocor

Indications for Use:

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Abbreviation	*Name*	*Unit*
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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___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K083879