

NOV - 1 2011



Date of Summary	April 5, 2011
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Applicant	Innovision A/S                      Phone: +45 65 95 91 00 Lindvedvej 75                      Fax: +45 65 95 78 00 DK-5260 Odense S                info@innovision.dk Denmark <a href="http://www.innovision.dk">www.innovision.dk</a>
Device Name	LCI Option for Innocor
Common Name	Pulmonary function test equipment
Classification	<b><i>LCI Option for Innocor – K102047</i></b> Calculator, pulmonary function data Regulation Number: 21 CFR §868.1880 Product Code: BZC Panel Code: Anesthesiology Device Class: II
Legally Marketed Predicate Devices	The LCI Option for Innocor is substantially equivalent in respect to the intended use, design and method of operation to the following legally marketed devices:  <i>Predicate Device No. 1</i> Name: Innocor

	<p>510(k) number: K051907                      Manufacturer: Innovision A/S, Denmark</p> <p><i>Predicate Device No. 2</i>                      Name: Cardiopulmonary Exercise Testing Option                      510(k) number: K071911                      Manufacturer: Innovision A/S, Denmark</p> <p><i>Predicate Device No. 3</i>                      Name: Spirometry Option                      510(k) number: K083879                      Manufacturer: Innovision A/S, Denmark</p> <p><i>Predicate Device No. 4</i>                      Name: COSMED QUARK                      510(k) number: K001174                      Manufacturer: COSMED S.r.l., Italy</p> <p><i>Predicate Device No. 5</i>                      Name: SensorMedics Vmax Series Pulmonary/Metabolic System                      510(k) number: K942211                      Manufacturer: SensorMedics</p>
<p>Device Description</p>	<p><b>Innocor</b> 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, b) metabolic parameters including oxygen uptake by means of a breath-by-breath gas exchange method, c) spirometry parameters by means of forced respiratory maneuvers, and d) peripheral airway function by means of multiple-breath inert gas washout.</p>

	<p><b>The basic Innocor</b> provides cardiac output (CO) as 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. The disappearance curve for the blood soluble gas is used to calculate pulmonary blood flow (PBF), which in the absence of a significant intrapulmonary shunt is equal to cardiac output. The functional residual capacity (FRC) is determined from the dilution of the relatively insoluble gas during the same maneuver.</p> <p><b>The LCI Option for Innocor</b>, used alone or in conjunction with the entire Innocor system, provides information on lung volume and peripheral airway function.</p> <p>The LCI is calculated as the cumulative expired volume (<math>V_{CE}</math>) required to clear the inert tracer gas from the lungs during normal breathing, minus the product of the number of wash-out breaths and the external dead space outside the lips, divided by the subject's Functional Residual Capacity (FRC). FRC is the amount of air that stays in the lungs (up to the lips) after a normal expiration. In other words, LCI represents the number of lung volume turnovers (i.e. FRCs) that the subject must breathe to clear the inert tracer gas from the lungs (by convention, to an end-tidal concentration of <math>1/40^{\text{th}}</math> of the starting concentration over three subsequent breaths).</p> <p>Innocor uses a combination of two techniques to determine the LCI, using <math>SF_6</math> as the inert tracer gas:</p> <p>Inert gas rebreathing (IGR) is used for rapid wash-in of a very small amount of <math>SF_6</math> until an even concentration is obtained in the lungs before the wash-out can start. This allows accurate determination of the functional residual capacity (FRC) by gas</p>
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	<p>analysis alone.</p> <p>This is followed by multiple-breath wash-out (MBW) for determination of the cumulative expired volume (<math>V_{CE}</math>) required to clear the <math>SF_6</math> from the lungs.</p> <p>The Innocor device is a compact and portable point-of-care device. The hardware in the LCI Option for Innocor is identical to that used in the Innocor Diagnostic Programmable Computer (K051907) and the Cardiopulmonary Exercise Testing Option to Innocor (K071911).</p> <p>The combined rebreathing/multiple breath wash-out test performed with the LCI Option for Innocor requires accurate measurements of the respiratory flow and the concentration of <math>SF_6</math> at the mouth during inspiration (inhalation) and expiration (exhalation). The Innocor device measures the flow and <math>SF_6</math> concentration by means of a pneumotachometer and a photoacoustic infrared gas analyzer, respectively, while the patient takes multiple breaths over a period of time through a pneumatically activated respiratory valve unit (RVU). The rebreathing gas mixture for wash-in of <math>SF_6</math> is filled into a rubber bag prior to testing.</p>
Intended Use and Indications	<p>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).</p> <p>The specific parameters measured by the Innocor LCI Option include:</p>

	<table border="1"> <thead> <tr> <th data-bbox="522 185 732 273"><i>Abbreviation</i></th> <th data-bbox="732 185 1143 273"><i>Name</i></th> <th data-bbox="1143 185 1401 273"><i>Unit</i></th> </tr> </thead> <tbody> <tr> <td data-bbox="522 273 732 351">LCI</td> <td data-bbox="732 273 1143 351">Lung Clearance Index</td> <td data-bbox="1143 273 1401 351">(none)</td> </tr> <tr> <td data-bbox="522 351 732 430">FRC</td> <td data-bbox="732 351 1143 430">Functional Residual capacity</td> <td data-bbox="1143 351 1401 430">L [BTPS]</td> </tr> </tbody> </table>	<i>Abbreviation</i>	<i>Name</i>	<i>Unit</i>	LCI	Lung Clearance Index	(none)	FRC	Functional Residual capacity	L [BTPS]
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LCI	Lung Clearance Index	(none)								
FRC	Functional Residual capacity	L [BTPS]								
<p>Summary of technological characteristics compared to predicate devices</p>	<p><b>Comparison with predicate device Innocor with options [K051907, K071911, and K083879]:</b></p> <p>The hardware in the LCI Option for Innocor is identical to that used in the predicate devices. The connection of the patient and the operation of the device are similar in that the wash-in is performed by rebreathing as in the basic Innocor (K051907), and the wash-out is performed by breathing room air in an open-circuit breath-by-breath measurement as in the Cardiopulmonary Exercise Testing Option (K071911). The gas mixture is the same as that used with Innocor and approved by the FDA as an integral part of the device (K051907). Thus, only the software is different from previous models.</p> <p><b>Comparison with predicate device COSMED QUARK [K001174]:</b></p> <p>Both the LCI Option for Innocor and the COSMED QUARK predicate device are indicated for use in pulmonary function testing to measure the wash-out of a gas from the lungs during a multiple-breath procedure in open-circuit mode. The LCI Option for Innocor performs the same LCI functions as the COSMED QUARK, by providing lung function measurements of FRC and LCI from analysis of a wash-out curve. Although there are some minor descriptive characteristics differences between the LCI</p>									

	<p>Option for Innocor and the COSMED QUARK, performance data from bench testing demonstrates substantial equivalence. The performance of the LCI Option for Innocor has been evaluated against a calibration syringe for FRC determination and data from a simulation for LCI determination. Performance data demonstrates that the hardware and software of the LCI Option for Innocor is substantially equivalent to a legally marketed predicate diagnostic device for LCI determination.</p> <p>Further, except for the way the indicator gas is washed in and the way FRC is determined, the LCI Option for Innocor meets the relevant recommendations in the Official American Thoracic Society/European Respiratory Society Statement: Pulmonary Function Testing in Preschool Children, Am J Respir Crit Care Med Vol 175. pp 1304–1345, 2007, Section 7: The Multiple-Breath Inert Gas Washout Technique.</p> <p><b>Comparison with predicate device SensorMedics Vmax Series Pulmonary/Metabolic System [K942211]:</b></p> <p>Both the LCI Option for Innocor and the SensorMedics Vmax Series Pulmonary/Metabolic System (K942211) are intended to measure LCI, and are for use in children and adults.</p> <p>The SensorMedics Vmax Series Pulmonary/Metabolic System was granted premarket clearance based, in part, on the Vmax calculating and providing LCI as one of the Distribution Parameters in the device’s Normal Predicted Equation Sets.</p> <p>The numerator and denominator of the fraction which defines LCI in the Vmax are defined in the Vmax 510(k) submission by reference to the cited article titled “A NEW INDEX OF THE INTRAPULMONARY MIXTURE OF INSPIRED AIR” by Margaret R. Becklake, Thorax (1952), 7, 111. More specifically,</p>
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	<p>the numerator and denominator of the fraction which defines LCI are defined in the Becklake article as: Litres ventilation required to wash 90% F.R.A. free of N<sub>2</sub> / 90% F.R.A.</p> <p>The LCI Option for Innocor employs a substantially equivalent method of measuring LCI, using essentially the same indexes and providing the same information.</p>
<p>Performance Testing / Summary of Substantial Equivalence (SE)</p>	<p>The LCI Option for Innocor has been evaluated against a calibration syringe simulating the lungs for FRC measurement (in the same way as for the predicate device, Innocor), and data obtained from a bench test using a calibration syringe to simulate the lungs has been compared with data from a simulation model of an LCI wash-out test. Performance data demonstrates that the hardware and software of the LCI Option for Innocor is as safe, as effective, and performs as well as or better than the predicate devices and thus that the device is substantially equivalent to the predicate devices.</p>
<p>Compliance with Recommendations</p>	<p>Except for the way the indicator gas is washed in and the way FRC is determined, the LCI Option for Innocor has been developed in accordance with the Official American Thoracic Society/European Respiratory Society Statement: Pulmonary Function Testing in Preschool Children, Am J Respir Crit Care Med Vol 175. pp 1304–1345, 2007, Section 7: The Multiple-Breath Inert Gas Washout Technique.</p> <p>The Statement includes the following remarks:</p> <ul style="list-style-type: none"> <li>- MBW is performed routinely in preschool children in only a limited number of laboratories, presumably because suitable equipment is not commercially available.</li> <li>- Several different inert marker gases with low solubility in</li> </ul>

	<p>blood and tissues can be used for MBW. The most well known is nitrogen (N<sub>2</sub>), which can be washed out from the lungs by letting the patient breathe pure oxygen (100% O<sub>2</sub>). Other gases, such as argon (Ar), helium (He), or sulfur hexafluoride (SF<sub>6</sub>), may also be used, but measuring these gases may require expensive equipment, such as a mass spectrometer.</p>
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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.

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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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

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

### 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]

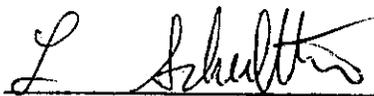
Prescription Use   X    
(Part 21 CFR 801 Subpart D)

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