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510(k) Summary

Applicant	Innovision A/S Lindvedvej 75 DK-5260 Odense S Denmark
Manufacturer	Same
Device Name	Innocor™
Common Name	Computer, diagnostic, programmable
Classification	Relevant Device Information: Class II Panel Code: Cardiovascular Product Code(s): DQK Regulation: §870.1425
Summary of Substantial Equivalence	Innocor has been shown by clinical testing to be substantially equivalent in respect to its intended use to measure cardiac output to two predicate technologies: 1) Thermodilution Cardiac Output Computers (American Edwards Laboratories) K872529 and K830892 and 2) the Direct Fick Method preamendment calculation method. The pulse oximeter component in the Innocor has been shown to be substantially equivalent to the ▪ K970763 MTS Option for the ESCORT II Monitor (Attachment 10A) ▪ K982776 Model 9303 Neonatal/Adult Vital Signs Monitor (See Attachment 2D) ▪ K021138 SleepScreen and ApnoeScreen Cardio (Attachment 10B) The NIBP component option in the Innocor has been shown to be substantially equivalent to the ▪ K032363 Zoll M-Series (NIBP Option) ▪ K051703 Clever TD-3018ATM Blood Pressure Monitor
Device Description	Innocor is a compact point-of-care device intended to be used for measurement of a) cardiac output (CO) utilizing inert gas rebreathing (IGR) technology and b) other hemodynamic parameters. Two Models will be made available initially in the U.S.: ▪ Innocor ▪ Innocor with NIBP option With the NIBP module option, the device will provide values for the hemodynamic parameters included in the Indications for Use below.

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Intended Use and Indications	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

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.

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

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____ **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)

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