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.

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,

B Zuckerman for

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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K071911