DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Combination Products
15800 Crabbs Branch Way
Suite 200, HFG-3
Rockville, MD 20855

Food and Drug Administration
Rockville MD 20857

August 27, 2004

[redacted]
70 W. Madison Street
Suite 3300
Chicago, IL 60602

Re: Request for Designation
Innocor
Our file: RFD 2004.039
Dated: July 27, 2004
Received and Filed: July 27, 2004

Dear [redacted]

The Food and Drug Administration (FDA) has completed its review of the request for designation (RFD) you submitted for the product Innocor, on behalf of INNOVISION A/S, on July 27, 2004. The Office of Combination Products filed the RFD on July 27, 2004. As explained below, we conclude that Innocor is a device that will be reviewed and regulated by the Center for Devices and Radiological Health (CDRH) under the medical device provisions of the Federal Food, Drug, and Cosmetic Act (the act).

Description of the Product

Innocor is a system that measures a number of [redacted] parameters, including cardiac output. Measuring cardiac output requires the patient to breathe oxygen mixed with minute quantities of [redacted] which is blood soluble, and [redacted] which has poor solubility in blood. [redacted] is absorbed by the blood as it passes through the lungs at a rate that is proportional to blood flow. [redacted] stays in the gas phase and is an indicator of lung volume. Innocor measures the levels of [redacted] and [redacted] using [redacted] to obtain a measure of cardiac output.

The Innocor system consists of a canister containing [redacted], [redacted],[1] the [redacted], and various other diagnostic options not at issue here. In 2003, INNOVISION [redacted]. In [redacted] CDRH questioned whether inhalation of [redacted] might be drugs, [redacted] Because the only issue is whether the inhaled gases are drugs or devices, INNOVISION addressed only that issue in the RFD.

INNOVISION argues that [redacted] are devices when used in Innocor. According to the RFD, Innocor measures the disappearance of [redacted] from the lungs into the blood, and [redacted] used to calculate lung volume. According to the RFD, [redacted] meet the definition of a device because neither achieve their primary intended purpose through chemical or metabolic action.

[1] [redacted]

Product Classification: Device

We have considered the information in the RFD and discussed the issues with staff in CDRH, and the Center for Drug Evaluation and Research (CDER). We conclude that Innocor is appropriately regulated by CDRH as a device.

The purpose of Innocor is to deliver [ ] to the lungs to determine cardiac output through the use of [ ] In this case it is clear that the [ ] and the canister containing [ ] meet the statutory definition of a device contained in Section 201(h) of the act.[2] We believe the device provisions of the Act will enable us to adequately evaluate [ ] to assure that your device is safe and effective for its specific intended uses.[3] This classification and assignment is consistent with the Intercenter Agreement between CDER and CDRH, section VII(C).

CDRH's Division of Cardiovascular Devices, Cardiac Electrophysiology & Monitoring Devices Branch, will have lead responsibility for the premarket review and regulation of Innocor. For further information about review requirements, please contact Elias Mallis, Chief, Cardiac Electrophysiology & Monitoring Devices Branch, Division of Cardiovascular Devices, CDRH, at 301-443-8517. Please include a copy of this letter with your initial submission.

You may request reconsideration of the classification or assignment of your product within 15 days of receipt of this letter. If you wish to request reconsideration, or for any other questions about this letter, please contact us at 301-427-1934. Finally, the Office of Combination Products is available to you as a resource for questions or issues that may arise throughout the development of your product. You may reach us at the above address, or by email at combination@fda.gov.

Sincerely,

Suzanne O'Shea
Product Classification Officer

cc: Elias Mallis

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[2] A device is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; or intended to affect the structure or function of the body of man. A device may not achieve its primary intended purposes through chemical or metabolic action within or on the body of man. Section 201(h) of the Act; 21 U.S.C. § 321(h).

[3] Please note that CDRH will determine the appropriate type of device application for Innocor.