K031983

SEP 1 5 2003

EXHIBIT #1

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is:_____.

1. Submitter's Identification:

Inovo, Inc.
3786 Mercantile Avenue
Naples, FL 34104

Date Summary Prepare: June 25, 2003

Contact Person: Mr. Kevin Confoy
General Manager

2. Name of the Device:

Inovo, Inc. Economizer Conserving Regulator

3. Predicate Device Information:

1. K#010747, OPC Oxygen Conserving Regulator, Model AHG, Western Medica, West Lake, Ohio

2. K#992659, O_2n Demand II, Victor Model OCPR-II, and Oxygen Conserving Pressure Regulator-II (OCPR-II) Victor Equipment Company, Denton, Texas

4. Device Description:

The Inovo, Inc., Economizer Conserving Regulator is a high pressure oxygen regulator and conserving device that is combined into a single compact unit. It operates in the same manner as traditional oxygen pressure regulators with the added benefit of having a conserving device included. It is constructed with an aluminum one piece body with all brass in the high pressure zones. The system is designed for an ambulatory patient with a high pressure oxygen cylinder. This unit requires no electrical power source. It operates with an operating pressure of 200 to 3000 psig and a nominal outlet pressure of 22 psi.

The device can function as a standard continuous flow regulator or as a conserving device which will double a patient's ambulatory time over that of a continuous oxygen system.

In conserving mode, the flow of oxygen is controlled by the patients inhalation and exhalation, which triggers a sensing diaphragm within the control module. As a result, the unit starts flowing oxygen when the user begins the inhalation cycle. Conversely, the unit shuts off the flow of oxygen when the user ceases inhalation.

It includes a click style flow control with selectable outlet flow that ranges 1 to 6 LPM by .5 LPM increments. The device can easily be switched between continuous or conserve mode without turning the device off.

The device uses a dual lumen cannula attached to two outlet ports. The first port senses the inhalation of the patient . The second port delivers the oxygen. In the "Conserve" mode, the device should be used only with the Hudson Dual Lumen Cannula (K# 961150) or a cannula with the same pneumatic characteristics.

5. **Intended Use:**

The Economizer Conserving Regulator is used to deliver a prescribed flow of gas to the patient while conserving gas, by sensing the patient inhalation cycle and supplying gas only during that phase of breathing.

6. **Comparison to Predicate Devices:**

The Inovo, Inc. Economizer Conserving Regulator is substantially equivalent to the Western Medica OPC Oxygen Conserving Regulator, K#010747 and the Victor Equipment Company O_2n Demand II, Victor Model OCPR-II, and Oxygen Conserving Pressure Regulator-II (OCPR-II), K# 992659. These predicate devices were cleared with the same indications for use as our device.

Similarities include features of the device, input operating pressure, outlet pressure, selectable outlet flows, oxygen conservation, inlet configuration, outlet connection, gauge and trigger point. There are few differences such as unit weight and response time. A major feature is a compact aluminum body with brass in all high pressure zones.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Performance Testing Included:

- ASTM G175 (formerly PS 127.00)
- Conservation Test
- Flow Regulation Test
- Flow Response Test
- Proof Pressure Test
- Hydrostatic Test

- Environment Testing

8. Discussion of Clinical Tests Performed:

Not Applicable

9. Conclusions:

The subject device, the Inovo, Inc. Economizer Conserving Regulator has the same intended use as the predicate devices, the Western Medica OCD Oxygen Conserving Regulator and the Victor O_2n Demand II OCPR-II. Moreover, bench testing contained in our submission and non-clinical testing supplied demonstrates that there are no differences in their technological characteristics, thereby not raising any new questions of safety and effectiveness. Thus, the Inovo, inc. Economizer Conserving Regulator is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 5 2003

Inovo, Incorporated
c/o Ms. Susan D. Goldstein-Falk
mdi Consultants, Incorporated
55 Northern Blvd, Suite 200
Great Neck, New York 11021

Re: K031983
Trade/Device Name: Economizer Conserving Regulator
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: NFB
Dated: June 25, 2003
Received: June 26, 2003

Dear Ms. Goldstein-Falk:

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 (301) 594-4646. 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/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit B

510(k) Number (if known): K031983

Device Name: Inovo, Inc. Economizer Conserving Regulator

Indications For Use:

The Economizer Conserving Regulator is used to deliver a prescribed flow of gas to the patient while conserving gas, by sensing the patient inhalation cycle and supplying gas only during that phase of breathing.

(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

510(k) Number: K031983

Prescription Use ✓ **(Per 21 CFR 801.109)** OR **Over-The Counter Use** _____ **(Optional Format 1-2-96)**