SEP 2 1 2005

EXHIBIT #1

510(K) SUMMARY

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.

The assigned 510(k) number is: K051540

1. Submitter's Identification:

Inovo, Inc.
2975 S. Horseshoe Drive
Naples, Fl. 34104

Date Summary Prepared: June 9, 2005

Contact Person: Mr. Kevin W. Confoy
General Manager

2. Name of the Device:

Inovo, Inc. Independence Conserving Regulator

2a. Class and Product Code

Class II , Product Code NFB , Anesthesiology Panel

3. Predicate Device Information:

1. Inovo Economizer (K031983)
2. DeVilbiss PD1000 (K020329)
3. Chad Oxymatic (K003455)

4. Device Description:

The Inovo, Inc. Independence Conserving Regulator is a high pressure oxygen regulator and conserving device that is combined into a single compact unit. It is designed to extend the use time of oxygen cylinders. The Independence senses the start of inhalation and immediately releases a short "pulse" of oxygen to the patient. Since all of the "pulse" of oxygen finds it way deep into the lungs, less oxygen is required to accomplish the same effect as traditional continuous-flow oxygen regulators.

The Independence Conserving Regulator contains an integral regulator with a CGA 870 style yoke. The regulator portion reduced the pressure to about 22PSIG. The Independence then delivers oxygen to the patient by sensing the beginning of inhalation using a pressure switch, which opens a solenoid valve for a specific period of time controlled by a microprocessor. The unit is designed to deliver 16 cc/lpm of oxygen to the patient at flows from 1 LPM to 6 LPM. The unit is powered by a single "AA" battery. The Independence

also has a continuous flow back-up mode that delivers selectable continuous flow in the event of battery or device failure.

The device has a two-color LED to indicate battery status. By depressing a "Battery test" switch, the device will show a Green light to indicate the battery is good. When the battery is below 0.9 vDC, the LED will be Red, indicating the battery must be changed. Under any circumstance, the "Continuous" mode can supply oxygen therapy in the event of battery failure.

Patient inspiration is detected by a pressure switch set by the manufacturer in the range of 0.10 to 0.35 cm H2O. The device is capable of delivering a bolus of oxygen at the beginning of the patient's inhalation at breathing rates up to 40 breaths per minute (BPM). Patients with more rapid breathing rates than 40 BPM will cause the device to "skip" breaths.

5. **Intended Use:**

The Independence Conserving Regulator is used to deliver a prescribed flow of medical grade oxygen to the patient while conserving gas from a high-pressure cylinder, by sensing the patient inhalation cycle and supplying gas only during that phase of breathing.

6. **Comparison to Predicate Devices:**

The Inovo, Inc. Independence Conserving Regulator is substantially equivalent to the Inovo Economizer (K031983), DeVilbiss PD 1000 (K020329) and the Chad Oxymatic (K003455). These predicate devices were cleared with the same indications for use as our device. The DeVilbiss and Chad devices are electronic conserving devices. The Inovo Economizer is a pneumatic device.

Similarities include features of the device, input operating pressures, outlet pressure, selectable outlet flows, oxygen conservation, inlet configuration, outlet connection, gauge, and trigger point. A major feature is a compact aluminum body with all brass in high pressure zones.

Similarities include features of the device attached as Exhibit #2.

There are two technological characteristic differences between the Independence and the predicate devices.

a. Timing

The Independence Conserving Regulator has a fixed valve open time of 500ms, which is programmed into the microprocessor. To achieve various "pulse" volumes, the device uses various flow rates. Predicate electronic devices use a fixed flow rate of approximately 10-12 LPM and vary the valve open time between 100ms and 600ms to achieve various "pulse" volumes.

There is no effect on safety and effectiveness.

b. Delivery valve

The Independence Conserving Regulator uses battery power to operate a small "pilot" solenoid valve and regulated oxygen pressure to operate the pneumatic delivery valve. Predicate electronic devices rely on battery power to operate a solenoid that controls a delivery valve. The dual-valve methodology extends battery life by nearly 40 times. The dual-valve technology used in the Independence is common in pneumatic conserving devices, including the Inovo Economizer (K031983)

There is no effect on safety and effectiveness.

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

Performance Testing Included:

- Promoted Ignition ASTM G175
- Hydrostatic Test
- Proof Pressure Test
- Conservation Test
- Flow Regulation Test
- Environmental Testing
- Electromagnetic Compatibility

8. **Discussion of Clinical Test Performed**

Not Applicable

8. **Conclusions:**

The subject device, the Inovo, Inc. Independence Conserving Regulator has the same intended use as the predicate devices, the Inovo Economizer (K031983), DeVilbiss PD1000 (K020329) and the Chad Oxymatic (K003455). Moreover, bench testing contained in our submission and non-clinical testing supplied demonstrates that there are no differences in their performance characteristics, thereby not raising any new questions of safety and effectiveness. Thus, the Inovo, Inc. Independence 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 2 1 2005

Mr. Kevin W. Confoy
General Manager
Inovo, Incorporated
2975 S. Horseshoe Drive
Naples, Florida 34104

Re: K051540
Trade/Device Name: Inovo, Inc. Independence Conserving Regulator
Regulation Number: 21 CFR 868.5905
Regulation Name: Non-Continuous Ventilation (IPPB)
Regulatory Class: II
Product Code: NFB
Dated: August 24, 2005
Received: August 25, 2005

Dear Mr. Confoy:

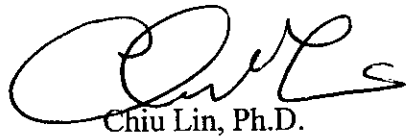
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

EXHIBIT B

Indications for Use

510(k) Number (if known): K051540

Device Name: Inovo, Inc. Independence Conserving Regulator

Indication For Use:

The Inovo Independence Conserving Regulator is used to deliver a prescribed flow of medical-grade oxygen to the patient while conserving gas from a high-pressure oxygen cylinder, by sensing the patient inhalation cycle and supplying gas only during that phase of breathing.

Prescription Use ___X___ **(Per 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

510(k) Number K051540