

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: K060751.

1. Submitter's Identification:

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

Date Summary Prepared: March 10, 2006

Contact Person: Mr. Michael T. Dildine
Quality Assurance Manager

2. Name of the Device:

Inovo, Inc. AccuPulse Conserving Regulator

3. Class and Product Code

Class II , Product Code NFB , Anesthesiology Panel

4. Predicate Device Information:

1. Precision Medical Inc. Easy Pulse 5 (K032018)
2. Chad Oxypneumatic Cypress Model 511 (K020475)
3. Inovo Economizer (K031983)

5. Device Description:

The Inovo, Inc. AccuPulse 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 AccuPulse 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 AccuPulse Conserving Regulator contains an integral regulator with a CGA 870 style yoke. The regulator portion reduced the pressure to about 22PSIG. The AccuPulse then delivers oxygen to the patient by sensing the beginning of inhalation using a diaphragm, which opens a sliding valve for a specific period of time controlled by pneumatic timing. The unit is designed to deliver 12 cc/lpm of oxygen to the patient at flows from 1 LPM to 6 LPM.

The AccuPulse also has a continuous mode that delivers selectable continuous flow in the event of device failure.

Patient inspiration is detected by a pressure-sensitive diaphragm 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.

6. Intended Use:

The AccuPulse 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.

7. Comparison to Predicate Devices:

The Inovo, Inc. AccuPulse Conserving Regulator is substantially equivalent to the Precision Medical Inc. Easy Pulse 5 (K032018), the Chad Oxypneumatic Cypress Model 511 (K020475) and the Inovo Economizer (K031983). These predicate devices were cleared with the same indications for use as our device.

Similarities include features of the device, input operating pressures, outlet pressure, selectable outlet flows, oxygen conservation, inlet configuration, outlet connection (except the Economizer, K031983, which has a dual-lumen 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 is one technological characteristic difference between the AccuPulse and the predicate devices:

Timing

The AccuPulse Conserving Regulator has a sliding valve which connects the outflow of oxygen to the outlet port. Upon patient inhalation, sliding valve closes the passage between the sensing diaphragm and the outlet port and then opens a passage to allow oxygen to the patient. The valve does not allow any oxygen to contact the sensing diaphragm, thereby protecting the diaphragm. In addition, the valve does not allow the unit to pulse a second time until a defined interval has passed.

There is no effect on safety and effectiveness.

8. **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

9. **Discussion of Clinical Test Performed**

Not Applicable

10. **Conclusions:**

The subject device, the Inovo, Inc. AccuPulse Conserving Regulator has the same intended use as the predicate devices, the Inovo Economizer (K031983), Precision Medical (K032018) and the Chad (K020475). 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. AccuPulse Conserving Regulator is substantially equivalent to the predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2006

Mr. Michael T. Dildine
Quality Assurance Manager
Inovo, Incorporated
2975 S. Horseshoe Drive, Suite 600
Naples, Florida 34104

Re: K060751

Trade/Device Name: Inovo, Inc. AccuPulse Single Lumen Pneumatic
Conserving Regulator
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: NFB
Dated: July 12, 2006
Received: July 12, 2006

Dear Mr. Dildine:

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,



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

Indications for Use

510(k) Number (if known):

Device Name: Inovo, Inc. AccuPulse Single Lumen Pneumatic Conserving Regulator

Indication For Use:

The Inovo AccuPulse Single Lumen Pneumatic 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)

W. Male for AAB

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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