**510(K) SUMMARY FOR**
**THE INVACARE FLYER, Model XPO100**

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

The assigned 510(k) number is _____.

Date: July 10, 2007

DEC 1 2 2007

Submitted by: Invacare Corporation
Registration No. 1525712
One Invacare Way
Elyria, Ohio 44035-4190

Telephone: 440-326-6356
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Contact Person: Mr. Carroll Martin

Trade Name: The Flyer

Model: XPO100

Common Name: Oxygen Concentrator

Classification Name: Generator, Oxygen, Portable per 21 CFR 868.5440

Legally Marketed Predicate Device(s): Inogen One Oxygen Concentrator; K032818, May 13, 2004

Device Description: The Invacare Flyer is used by patients with respiratory disorders who require supplemental oxygen. The device can be used in the home, an institutional environment or in a vehicle or other mobile environment. The device is not intended to sustain or support life. The device is used with a nasal cannula to direct oxygen from the device to the patient.

The Invacare Flyer provides oxygen in pulsed demand flow dosages at settings of 1 through 5. The oxygen concentration level of the output gas ranges from 87% to 95.6%.

Standard power options include an AC to DC switching power supply operating from AC power outlet (120 VAC/ 60 Hertz nominal), a DC to DC switching power supply operating from accessory outlets typically found in a mobile vehicle type environment (12 VDC nominal) and an external rechargeable battery.

The Invacare Flyer uses a molecular sieve and pressure swing adsorption methodology to produce the oxygen gas output. Ambient air enters the device, is filtered and then compressed. This compressed air is then directed toward one of two nitrogen adsorbing sieve beds. Concentrated oxygen exits the

opposite end of the active sieve bed and is directed into an oxygen reservoir where it is delivered to the patient in specific volumes during the inhalation portion of a detected breath.

The basic technology of the Invacare Flyer is equivalent to other approved oxygen concentrators. The principles of operation are equivalent to the noted predicate device.

Intended Use: The Invacare Flyer is intended to be used by patients with respiratory disorders who require supplemental oxygen. It supplies a high concentration of supplemental oxygen and is used with a nasal cannula to channel oxygen from the concentrator to the patient. The Invacare Flyer can be used in a home, institution, vehicle and various mobile environments. The Invacare Flyer does not nor is it intended to sustain or support life.

Substantial Equivalence:

| **Features** | **The Invacare Flyer** | **Predicate Device Inogen One Oxygen Concentrator** |
|---|---|---|
| **510(k) Number** | **TBD** | **K032818** |
| **Date Cleared** | **TBD** | **05/13/2004** |
| **Intended Use** | The Invacare Flyer is intended to be used by patients with respiratory disorders who require supplemental oxygen. It supplies a high concentration of supplemental oxygen and is used with a nasal cannula to channel oxygen from the concentrator to the patient. The Invacare Flyer can be used in a home, institution, vehicle and various mobile environments. The Invacare Flyer does not nor is it intended to sustain or support life. | The Inogen One Oxygen Concentrator is used on a prescriptive basis by patients requiring supplemental oxygen. It supplies a high concentration of oxygen and is used with a nasal cannula to channel oxygen from the concentrator to the patient. The Inogen One Oxygen Concentrator may be used in a home, institution, vehicles and various mobile environments. |
| **Method by which Oxygen is Released** | Molecular sieve (mechanical) | Molecular sieve (mechanical) |
| **Process by which Oxygen is Released** | Pressure swing adsorption | Pressure swing adsorption |
| **Sieve Bed Material** | Synthetic zeolite | Synthetic zeolite |
| **Software/Hardware** | Analog and digital electronics with microprocessor | Analog and digital electronics with microprocessor |
| **Flow Control** | Microprocessor controlled valves | Microprocessor controlled valves |
| **Weight** | < 7.0 lbs. ( with non-removable internal battery) | 9.8 lbs. (device 8.3 lbs.; battery 1.5 lbs.) |
| **Size** | | |
| Height | 10.0" +/- 1" | 12.39" |
| Width | 7.0" +/- 1" | 6.00" |
| Depth | 4.3" +/- 1" | 11.62" |
| **Oxygen Purity** | 87% minimum at all flow rates | "Approximately 90%" |

| | | |
|---|---|---|
| **Flow Rates** | Pulse Flow – 1, 2, 3, 4, 5 | Pulse Flow – 1, 2, 3, 4, 5 |
| **Power Options** | AC power supply 100-240 V, 50/60 Hz; DC power supply 11-16 V | AC power supply 100-240V, 50/60 Hz; Mobile Power Charger for mobile DC use. |
| **Battery** | Li-ion, 14.8 Volt, 5.2 Ah | Li-ion, 14.8 Volt, 6.6 Ah |

As the chart above shows, the Invacare Flyer is comparable to its predicate. Both devices have the same intended use for the same patient population, extract oxygen from air using the same methodology, provide comparable oxygen purity and are powered in the same manner.

**Design Standards: The Invacare Flyer has been designed referencing the following standards:**

| Standard or Agency | Title |
|---|---|
| ASTM 1464-93 (2005) | Standard Specification for Oxygen Concentrators for Domiciliary Use |
| ISO 8359; 1996 | Oxygen Concentrators for Medical Use - Safety Requirements |
| UL 1097, 5th ed., 2004 | UL Standard for Safety for Double Insulation Systems for Use in Electrical Equipment, UL 1097 |
| UL 1431, 2nd ed., 1996 | UL Standard for Safety for Personal Hygiene and Health Care Appliances, UL1431 (with revisions from 2003) |
| EN 55011:1998 | Limits and methods of measurement of radio disturbance characteristics and medical (ISM) radio-frequency equipment |
| IEC 60601-1; 3rd ed. 2006 | Medical Electrical Equipment – Part 1 – General requirements for basic safety and essential performance |
| IEC 60601-1-2; 3rd ed. 2007 | Medical Electrical Equipment – Part 1-2 – Collateral standard: Electromagnetic compatibility |
| IEC 61000-3-2: 2005 | Electromagnetic compatibility (EMC). Limits. Limits for harmonic current emissions (equipment input current up to and including 16 A per phase) |
| EN 61000-3-3: 2005 | Electromagnetic compatibility (EMC). Limits. Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current <= 16 A per phase and not subject to conditional connection |
| IEC61000-4-2; 1.2 ed. 2001 | Electrostatic Discharge Immunity Test w/ Amendments 1&2 |
| IEC61000-4-3; 3rd ed. 2006 | Radiated, RF, Electromagnetic Field Immunity Test |
| IEC61000-4-4; 2nd ed. 2007 | Electrical Fast Transient/Burst Immunity Test w/ Amendments 1&2 |

| | |
|---|---|
| IEC61000-4-5; 2nd ed. 2005 | Surge Immunity Test |
| IEC61000-4-6; 1st ed. 2006 | Immunity to Conducted Disturbances Induced by RF fields w/ Amendments 1&2 |
| IEC61000-4-8; 1.1 ed. 2001 | Power Frequency Magnetic Field Immunity Tests |
| IEC61000-4-11; 4th ed. 2004 | Voltage Dips, Short Interruptions and Voltage Variations Immunity Tests w/ Amendment 1 |
| FDA Reviewer's Guide 93 | Reviewer Guidance for Premarket Notification Submissions |

**Performance Testing: The Invacare Flyer has been tested in accordance with the following:**

| Standard or Agency | Title |
|---|---|
| EN 60601-1-2; 2nd ed. 2001 | Medical Electrical Equipment – Sec 1.2 – Collateral standard: Electromagnetic compatibility |
| IEC 60601-1-2; 2.1 ed. | Medical Electrical Equipment – Sec 1.2 – Collateral standard: Electromagnetic compatibility |
| EN 55011:1998 | Limits and methods of measurement of radio disturbance characteristics and medical (ISM) radio-frequency equipment |
| CISPR 11: 2003 | Limits and methods of measurement of radio disturbance characteristics and medical (ISM) radio-frequency equipment |
| EN61000-4-3; 2002 | Radiated, RF, Electromagnetic Field Immunity Test |
| IEC61000-4-3; 2006 | Radiated, RF, Electromagnetic Field Immunity Test |
| EN 61000-4-4; 1995 | Electrical Fast Transient/Burst Immunity Test |
| IEC 61000-4-4; 2004 | Electrical Fast Transient/Burst Immunity Test |
| EN 61000-4-5; 1995 | Surge Immunity Test |
| IEC 61000-4-5; 2005 | Surge Immunity Test |
| EN 61000-4-6; 1996 | Immunity to Conducted Disturbances Induced by RF fields |
| IEC 61000-4-6; 2006 | Immunity to Conducted Disturbances Induced by RF fields |
| EN 61000-4-8; 2001 | Power Frequency Magnetic Field Immunity Tests |

| | |
|---|---|
| EN 61000-4-11; 1995 | Voltage Dips, Short Interruptions and Voltage Variations Immunity Tests |
| IEC 61000-4-11; 2004 | Voltage Dips, Short Interruptions and Voltage Variations Immunity Tests |
| EN 61000-3-2: 2000 | Limits for Harmonic Current Emissions |
| IEC 61000-3-2: 2005 | Limits for Harmonic Current Emissions |
| EN 61000-3-3: 1995 | Voltage fluctuations and flicker Tests |
| IEC 61000-3-3: 2005 | Voltage fluctuations and flicker Tests |
| IEC 60601-1: 2nd ed. 1998 with Amendment 1: 1991 with Amendment 2: 1995 | Medical Electrical Equipment, Part 1: General requirements for basic safety and performance |
| UL 60601-1: 1st ed. 2003 | Medical Electrical Equipment, Part 1: General requirements for basic safety and performance |
| CSA 601.1 M90 | Medical Electrical Equipment, Part 1: General requirements for basic safety and performance |
| Quasi-Static Electric Field | Reviewer Guidance for premarket notification submissions 1993 |
| FDA Reviewer's Guide:1993 | Electrostatic Discharge Immunity Test per Sec. m,7,ii,a. |
| FDA Reviewer's Guide:1993 | Reviewer Guidance for Premarket Notification Submissions |

Performance Data: The performance data found in this submission shows that the Invacare Flyer performs as intended and in a manner that is substantially equivalent to the predicate device.

Conclusion: The data presented in this submission shows that the Invacare Flyer performs as intended and in a manner that is substantially equivalent to the predicate devices.

## Executive Summary

### Device Description

The Invacare Flyer is used by patients with respiratory disorders who require supplemental oxygen. The device is not intended to sustain or support life.

The basic technology of the Invacare Flyer is equivalent to other approved oxygen concentrators. The principles of operation are equivalent to the noted predicate device. The oxygen concentration level of the output gas ranges from 87% to 95.6%. The oxygen is delivered to the patient through the use of a nasal cannula. When the demand for oxygen is detected, the oxygen is delivered through pulsed flow with pulse flow settings of 1 through 5.

The Invacare Flyer uses a molecular sieve and pressure swing adsorption methodology to produce the oxygen gas output. Ambient air enters the device, is filtered and then compressed. This compressed air is then directed toward one of two nitrogen adsorbing sieve beds. Concentrated oxygen exits the opposite end of the active sieve bed and is directed into an oxygen reservoir where it is delivered to the patient in specific volumes during the inhalation portion of a detected breath.

The Invacare Flyer is capable of operation by the patient in a home environment, in an institutional environment, in a vehicle or other mobile environment. Device standard power options include an AC to DC switching power supply operating from AC power outlet (120 VAC/ 60 Hertz nominal), a DC to DC switching power supply operating from accessory outlets typically found in a mobile vehicle type environment (12 VDC nominal) and an external rechargeable battery.

The Invacare Flyer has several lights and indicators providing the user with information regarding the operation of the device:

1. Start-Up Indicator – the Flyer will briefly light all LEDs and output a brief audible beep when first turned on to indicate the unit is operational.

2. Breath Detect Indicator – the Flyer will output a defined pulse of oxygen each time it detects an inhalation. The blue flow setting indicator light will blink each time an inhalation is detected and the Flyer outputs a pulse of oxygen.

3. Internal Battery Charging Indicator – the battery gauge will be illuminated during charging to indicate the internal batter charge status. When the battery is fully charged, all four battery gauge display LEDs will illuminate continuously.

4. Low Battery Warning - when the Flyer's internal battery (or external battery, if applicable) charge level falls to 25% capacity, a brief audible beep will sound and the lowest level battery gauge display LED will blink.

5. Low Battery Alarm – when the Flyer's internal battery (or external battery, if applicable) charge level falls to 15% capacity, a brief audible double beep will sound and the lowest level battery gauge display LED will blink rapidly..

6. Battery Discharged Alarm - when the Flyer's internal battery (or external battery, if applicable) charge level falls to a minimum capacity, a brief audible triple beep will sound, the lowest level battery gauge display LED will blink very rapidly and the unit will shutdown.

7. No Breath Detect Alarm – when the Flyer is operating but does not sense breathing within a predetermined time period (e.g 60 seconds), a constant audible alarm sounds and the red alarm indicator light will illuminate continuously.

8. Breath Rate Over Capacity Alarm – if the breathing rate exceeds the capacity of the Flyer, a rapid audible beep sounds and the red alarm indicator light will illuminate intermittently.

9. System Too Hot/Cold for Start Alarm – if the Flyer senses temperatures outside factory set levels upon start-up, the unit will alarm with a rapid audible beep, the red alarm indicator light will illuminate continuously, the unit will not operate and the flow setting 1 & 2 blue indicator lights will illuminate.

10. System Too Hot/Cold Running Alarm – if the Flyer senses temperatures outside factory set levels during operation, the unit will alarm with a rapid audible beep, the red alarm indicator light will illuminate continuously, the unit will not operate and the flow setting 1 & 3 blue indicator lights will illuminate.

11. Battery Too Hot/Cold Alarm – if the Flyersinternal battery senses temperatures outside a factory defined temperature range while the unit is operating, the unit will alarm with a rapid audible beep, the red alarm indicator light will illuminate continuously, the unit will stop running and the flow setting 1 & 4 blue indicator lights will illuminate.

12. Stuck Button Alarm – During power up of the unit, if it detects that a button is stuck or being pressed too early, the unit will alarm with a rapid audible beep, the red alarm indicator light will illuminate continuously, the unit will not operate and the flow setting 1 & 5 blue indicator lights will illuminate.

13. Operating Alarm – If units detects abnormal operating conditions in the unit (such as over and under pressure), the unit will alarm with a rapid audible beep, the red alarm indicator light will illuminate continuously, the unit will not operate and the flow setting 3 & 4 blue indicator lights will illuminate.

14. Compressor Alarm – If units detects abnormal compressor conditions (such as Locked Rotor or RPM error), the unit will alarm with a rapid audible beep, the red alarm indicator light will illuminate continuously, the unit will not operate and the flow setting 4 & 5 blue indicator lights will illuminate.

15. System Alarm – If units detects abnormal system conditions (such as Watchdog Timer error), the unit will alarm with a rapid audible beep, the red alarm indicator light will illuminate continuously, the unit will not operate and the flow setting 3,4 & 5 blue indicator lights will illuminate.

**Intended Use:** The Invacare Flyer is intended to be used by patients with respiratory disorders who require supplemental oxygen. It supplies a high concentration of supplemental oxygen and is used with a

nasal cannula to channel oxygen from the concentrator to the patient. The Invacare Flyer can be used in a home, institution, vehicle and various mobile environments. The Invacare Flyer does not nor is it intended to sustain or support life.

**Device Comparison Table**

| Features | The Invacare Flyer | Predicate Device<br>Inogen One Oxygen Concentrator |
|---|---|---|
| **510(k) Number** | **TBD** | **K032818** |
| **Date Cleared** | **TBD** | **05/13/2004** |
| **Intended Use** | The Invacare Flyer is intended to be used by patients with respiratory disorders who require supplemental oxygen. It supplies a high concentration of supplemental oxygen and is used with a nasal cannula to channel oxygen from the concentrator to the patient. The Invacare Flyer can be used in a home, institution, vehicle and various mobile environments. The Invacare Flyer does not nor is it intended to sustain or support life. | The Inogen One Oxygen Concentrator is used on a prescriptive basis by patients requiring supplemental oxygen. It supplies a high concentration of oxygen and is used with a nasal cannula to channel oxygen from the concentrator to the patient. The Inogen One Oxygen Concentrator may be used in a home, institution, vehicles and various mobile environments. |
| **Method by which Oxygen is Released** | Molecular sieve (mechanical) | Molecular sieve (mechanical) |
| **Process by which Oxygen is Released** | Pressure swing adsorption | Pressure swing adsorption |
| **Sieve Bed Material** | Synthetic zeolite | Synthetic zeolite |
| **Software/ Hardware** | Analog and digital electronics with microprocessor | Analog and digital electronics with microprocessor |

| Features | The Invacare Flyer | Predicate Device Inogen One Oxygen Concentrator |
|---|---|---|
| **Flow Control** | Microprocessor controlled valves | Microprocessor controlled valves |
| **Weight** | < 7.0 lbs. (with internal battery) | 9.8 lbs. (device 8.3 lbs.; insertable battery 1.5 lbs.) |
| **Size:** | | |
| **Height** | 10.0" +/- 1" | 12.39" |
| **Width** | 7.0" +/- 1" | 6.00" |
| **Depth** | 4.3" +/- 1" | 11.62" |
| **Oxygen Purity** | 87% minimum at all flow rates | "Approximately 90%" |
| **Flow Rates** | Pulse Flow – 1, 2, 3, 4, 5 | Pulse Flow – 1, 2, 3, 4, 5 |
| **Power Options** | AC power supply 100-240 V, 50/60 Hz; DC power supply 11-16 V | AC power supply 100-240V, 50/60 Hz; Mobile Power Charger for mobile DC use. |
| **Battery** | Li-ion, 14.8 Volt, 5.2 Ah | Li-ion, 14.8 Volt, 6.6 Ah |

As the chart above shows, the Invacare Flyer is comparable to its predicate. Both devices have the same intended use for the same patient population, extract oxygen from air using the same methodology, provide comparable oxygen purity and are powered in the same manner. The main differences between the two devices are the weight and physical dimensions. Testing shows that these differences have no effect on safety or effectiveness.

**Performance Testing:** The Invacare Flyer has been tested in accordance with the following:

| | |
|---|---|
| EN 60601-1-2; 2nd ed. 2001 | Medical Electrical Equipment – Sec 1.2 – Collateral standard: Electromagnetic compatibility |
| IEC 60601-1-2; 2.1 ed. | Medical Electrical Equipment – Sec 1.2 – Collateral standard: Electromagnetic compatibility |
| EN 55011:1998 | Limits and methods of measurement of radio disturbance characteristics and medical (ISM) radio-frequency equipment |
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| IEC 61000-4-4; 2004 | Electrical Fast Transient/Burst Immunity Test |
| EN 61000-4-5; 1995 | Surge Immunity Test |
| IEC 61000-4-5; 2005 | Surge Immunity Test |
| EN 61000-4-6; 1996 | Immunity to Conducted Disturbances Induced by RF fields |
| IEC 61000-4-6; 2006 | Immunity to Conducted Disturbances Induced by RF fields |

| | |
|---|---|
| EN 61000-4-8; 2001 | Power Frequency Magnetic Field Immunity Tests |
| EN 61000-4-11; 1995<br>IEC 61000-4-11; 2004 | Voltage Dips, Short Interruptions and Voltage Variations Immunity Tests<br>Voltage Dips, Short Interruptions and Voltage Variations Immunity Tests |
| EN 61000-3-2: 2000<br>IEC 61000-3-2: 2005 | Limits for Harmonic Current Emissions<br>Limits for Harmonic Current Emissions |
| EN 61000-3-3: 1995<br>IEC 61000-3-3: 2005 | Voltage fluctuations and flicker Tests<br>Voltage fluctuations and flicker Tests |
| IEC 60601-1: 2nd ed. 1998<br>with Amendment 1: 1991<br>with Amendment 2: 1995 | Medical Electrical Equipment, Part 1: General requirements for basic safety and performance |
| UL 60601-1: 1st ed. 2003 | Medical Electrical Equipment, Part 1: General requirements for basic safety and performance |
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| Quasi-Static Electric Field | Reviewer Guidance for premarket notification submissions 1993 |
| FDA Reviewer's Guide:1993 | Electrostatic Discharge Immunity Test per Sec. m,7,ii,a. |
| FDA Reviewer's Guide:1993 | Reviewer Guidance for Premarket Notification Submissions |

The results of the testing have shown that the Invacare Flyer is safe and effective for its intended use and substantially equivalent to its predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 2 2007

Mr. Carroll L. Martin
Regulatory Affairs Manager
Invacare Corporation
One Invacare Way
P.O.Box 4028
Elyria, Ohio 44036-2125

Re: K071928
Trade/Device Name: Invacare Flyer, Model XPO100
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: November 8, 2007
Received: November 9, 2007

Dear Mr. Martin:

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.

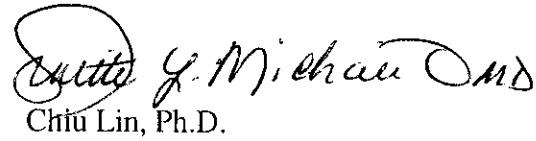
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0115. 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,
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Office of Device Evaluation
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Radiological Health

Enclosure

# Indications for Use

**510(k) Number (if known):**

**Device Name: Invacare Flyer, Model XPO100**

**Indications for Use:** The Invacare Flyer (Model XPO100) is intended to be used by patients with respiratory disorders who require supplemental oxygen. It supplies a high concentration of supplemental oxygen and is used with a nasal cannula to channel oxygen from the concentrator to the patient. The Invacare Flyer can be used in a home, institution, vehicle and various mobile environments. The Invacare Flyer does not nor is it intended to sustain or support life.

Prescription Use ___✔___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K071928