

K012706

**510(K) SUMMARY**

MAR 07 2003

**IM2001 Pulse Oximeter**

**510(k) Number K012706**

(Revised 7-22-02)

**Applicant's Name:** Cybro Medical Ltd. (Subsidiary of Imagyn, Inc.)  
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**Contact Person:** Julie Powell  
Imagyn Medical Technologies, Inc.  
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**Trade Name:** IM2001 Pulse Oximeter

**Classification Name:** Oximeter

**Classification:**

The FDA has classified pulse oximeters as class II devices (product code 74DQA, Regulation No. 870.2700) and they are reviewed by the Cardiovascular Panel.

**Predicate Device:**

N-395 Pulse Oximeter (Nellcor Puritan Bennett, Inc) cleared under K991823 and K993637 when operates with its RS-10 sensor (Nellcor Puritan Bennett, Inc) cleared under K904039.

**Intended Use:**

The IM2001 Pulse Oximeter is indicated for the continuous, non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO<sub>2</sub>) and pulse rate. For use with pediatric and adult population, in hospitals, hospital-type facilities and intra-hospital transport environment.

**Device Description:**

The IM-2001 Pulse Oximeter is designed for continuous, non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO<sub>2</sub>) and pulse rate based on the principal of Reflection. The device consists of a small and light-weight sensor and is intended to monitor arterial SaO<sub>2</sub> from the forehead.

IM2001 Pulse Oximeter consists of a sensor that emits and detects red and infrared light, a holder, a connecting cable, and a microprocessor-controlled monitoring console Signal Processing Unit (monitor). The monitor displays digital values of SpO<sub>2</sub> and Pulse Rate.

The IM2001 is intended for prescription use with adult and pediatric patients in hospitals, hospital-type facilities, and intra-hospital transport environments.

**Substantial Equivalence:**

Cybro Medical Ltd. believes that, based on calculations, validations, and performance testing results, the IM2001 Pulse Oximeter is substantially equivalent to its predicate device cited above without raising new safety and/or effectiveness issues.



MAR 07 2003

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Cybro Medical, Ltd.  
c/o Ms. Julie Powell  
Vice President of Quality Assurance and Regulatory Affairs  
Imagyn Medical Technologies, Inc.  
8850 M-89 Box 351  
Richland, Michigan 49083-9416

Re: K012706  
Trade/Device Name: IM2001 Pulse Oximeter  
Regulation Number: 21 CFR 870.2700  
Regulation Name: Oximeter  
Regulatory Class: Class II (two)  
Product Code: 74 DQA  
Dated: December 6, 2002  
Received: December 9, 2002

Dear Ms. Powell:

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

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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,

A handwritten signature in black ink that reads "Susan Runner". The signature is written in a cursive, flowing style.

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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K012706

Device Name: IM2001 Pulse Oximeter

Indications for Use:

The IM2001 Pulse Oximeter is indicated for the continuous, non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. For use with pediatric and adult population, in hospitals, hospital-type facilities and intra-hospital transport environment. For prescription use only.

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

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Prescription Use  OR Over the Counter Use   
(Per 21 CFR 801.109)



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

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