

SEP - 4 2003

510(k) Summary - ECOM CV4 System

510(k) Summary This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R. § 807.92.

Submitter Imagyn Medical Technologies, Inc.
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Irvine, CA 92614

Contact Person Julie Powell
Vice President Quality Assurance / Regulatory Affairs
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Date Prepared August 8, 2003

Name ECOM™ CV4 Endotracheal Cardiac Output Monitor

Classification Names Impedance plethysmograph

Device Classification Regulatory Class: II
Product Code: DSB
Classification Panels: Cardiovascular Device Panel
Regulation Number: 21 CFR 870.2770

Predicate Device(s) Imagyn Medical Technologies, Inc.
ECOM Endotracheal Cardiac Output Monitor
510(k) number K021174
Clearance date April 29, 2003

Performance Standards	Performance standards have not been established by the FDA under section 514 of the Federal, Food, Drug and Cosmetic Act
Device Description	<p>The ECOM CV4 System consists of an ECOM CV4 Endotracheal Tube and an integrated ECOM CV4 Monitor. The ECOM CV4 Monitor includes a Tube Cable, Arterial Pressure Cable, ECG Cable, ECG Lead Wire, and power cordset.</p> <p>The ECOM CV4 System applies a high frequency, low amplitude electrical current and measures the resulting voltage directly from the tracheal mucosa by way of an ECOM CV4 Endotracheal Tube. The ECOM CV4 Monitor will display the tube and surface R-Wave and the Impedance Waveforms as well as the patient's Cardiac Output (CO), Heart Rate (HR), Stroke Volume (SV), Systolic and Diastolic Pressures.</p>
Indications for Use	<p>The ECOM CV4 (Endotracheal Cardiac Output Monitor) System is intended for the monitoring of cardiac output by impedance cardiography while providing airway management by oral intubation with an ECOM Endotracheal Tube. The ECOM CV4 System is indicated for use in patients who are expected to be intubated for 24 hours or less and in whom an arterial pressure line is used.</p> <p>The ECOM CV4 System will display the R-Wave Detection and the Impedance Waveforms as well as the patient's Cardiac Output (CO), Stroke Volume (SV), Heart Rate (HR), Systolic and Diastolic Pressures.</p>
Nonclinical Performance	The ECOM CV4 System was tested and passed all required electrical safety, ASTM, and biocompatibility testing.
Clinical Performance	The ECOM CV4 System performance was tested with clinical data and the results met the acceptance criteria.
Conclusion	The ECOM CV4 System is substantially equivalent to the 510(k) cleared (K021174) ECOM System.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Imagyn Medical Technologies, Inc.
c/o Ms. Julie Powell
Vice President, Quality Assurance
Regulatory Affairs
1 Park Plaza, Suite 1100
Irvine, CA 92614

Re: K032491
Trade Name: ECOM CV4 Endotracheal Cardiac Output Monitor
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II (two)
Product Code: DSB
Dated: August 8, 2003
Received: August 12, 2003

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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

Warning: The irregular tracheal cuff surface of the ECOM tracheal tube presents a potential for local pressure injury to the trachea. The safety of the ECOM tracheal tube for more than 24 hours use has not been established. The ECOM tracheal tube should not be inserted when a duration of intubation longer than 24 hours can be anticipated.

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Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

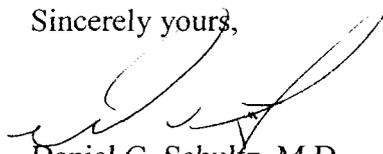
The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

If you desire specific information about the application of other labeling requirements to your device (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" (21 CFR 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,



Daniel G. Schultz, M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K032491

Device Name: ECOM CV4 Endotracheal Cardiac Output Monitor

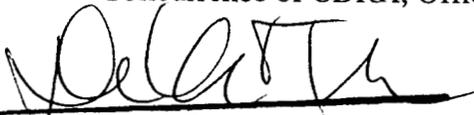
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The ECOM CV4 System will display the R-Wave Detection and the Impedance Waveforms as well as the patient's Cardiac Output (CO), Stroke Volume (SV), Heart Rate (HR), Systolic and Diastolic Pressure.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices

(Optional Format 3-10-98)

Prescription Use Only

510(k) Number K032491