September 19, 2017

ECOM Medical, Inc.,
% Cheryl Blake
Regulatory Affairs
27392 Capricho
Mission Viejo, California 92692

Re: K172196
Trade/Device Name: ECOM™ Cardiac Output Monitoring System
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: Class II
Product Code: DSB
Additional Product Codes: CBI
Dated: July 22, 2017
Received: July 25, 2017

Dear Cheryl Blake:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

[Signature]

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number (if known)
K172196

Device Name
ECOM Cardiac Output Monitoring System

Indications for Use (Describe)
The ECOM Cardiac Output Monitoring System is intended for the monitoring of cardiac output by impedance cardiography.

The ECOM System displays 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.

The ECOM 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.

The ECOM with the 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 Double Lumen Endobronchial Tube is used to isolate the left lung of a patient for surgery, one lung ventilation or one lung anesthesia. The ECOM Endobronchial Tube is indicated for use in thoracic surgery, bronchspirometry, for the administration of endobronchial anesthesia and other uses commonly associated with endobronchial tubes. The tube allows isolation and selective insufflation or deflation of either lung.

Type of Use (Select one or both, as applicable)

☑ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)
This section applies only to requirements of the Paperwork Reduction Act of 1995.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

- Department of Health and Human Services
- Food and Drug Administration
- Office of Chief Information Officer
- Paperwork Reduction Act (PRA) Staff
- PRAStaff@fda.hhs.gov

*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.*
510(k) Summary of Safety and Effectiveness

ECOM™ Cardiac Output Monitoring System

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21CFR 807.92, ECOM Medical, Inc. is hereby submitting the 510(k) Summary of Safety and Effectiveness for 510(k) number K172196 as of September 14, 2017.

A. Submitter

ECOM Medical, Inc
27127 Calle Arroyo, Suite 1905
San Juan Capistrano, CA 92576
USA

Establishment Registration: 13010770019

B. Applicant Correspondent

Cheryl Blake
Regulatory Consultant
27392 Capricho
Mission Viejo, CA 92692
cherylblake@cox.net
949-285-3517

C. Device Name

Proprietary Name: ECOM™ Cardiac Output Monitoring System
Common Name: Plethysmograph, impedance
Classification Name: Impedance plethysmograph
Regulation Number: 870.2770
Product Code: DSB
Regulatory Class: II
Panel: Cardiovascular

D. Predicate Device

Primary Device Name: ECOM Endotracheal Cardial Output Monitor System
Company Name: ECOM Medical via acquisition of ECOM division of Conmed
510(k): K131765

Secondary Device Name: Well Lead Endobronchial Tubes
Company Name: Well Lead Medical Device Instruments Ltd.
510(k): K092886
E. Device Description

The ECOM Cardiac Output Monitor System consists of a monitor, and various accessories. The line extension of the ECOM Double Lumen Endobronchial Tube to the systems line of Endotrachel tubes continues to apply a high frequency, low amplitude electrical current to a series of electrodes applied to the endobronchial tube. The resulting signals, when used in conjunction with an arterial pressure signal, allow for the calculation and display of Cardiac Output (CO), Cardiac Input (CI), Stroke Volume (SV), Stroke Volume Variation (SVV), Heart Rate (HR), Systemic Vascular Resistance (SVR), Systemic Vascular Resistance Index (SVRI), and systolic, diastolic and mean blood pressures. No changes have been made to the monitor system in K131765 or the endobronchial tube design in K092886.

F. Intended Use / Indications for Use

The ECOM Cardiac Output Monitoring System is intended for the monitoring of cardiac output by impedance cardiography.

The ECOM System displays 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.

The ECOM 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.

The ECOM with the 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 endotraheal tube.

The ECOM Double Lumen Endobronchial Tube is used to isolate the left lung of a patient for surgery, one lung ventilation or one lung anesthesia. The ECOM Endobronchial Tube is indicated for use in thoracic surgery, bronchspirometry, for the administration of endobronchial anesthesia and other uses commonly associated with endobronchial tubes. The tube allows isolation and selective insufflation or deflation of either lung.

G. Non-clinical Performance Testing

Non-clinical bench testing demonstrated the ECOM Endobronchial Cardiac Output Monitor System is substantially equivalent to the predicate with regard to intended use, materials, technology, and performance of the monitoring. Design verification testing, demonstrates the system, using the previously cleared monitor and software, monitors and displays 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. Material analysis demonstrates the patient contacting materials comply with the requirements of ISO 10993-1:2009.
H. Substantial Equivalence

The differences between the predicate and the new tube design do not raise any new risks of safety or efficacy. No changes have been made to the devices represented in K131765 and K092886. No changes have been made to the endobronchial tube design and only IFU has been updated to include the endobronchial tube supporting information. Additional supporting information per this premarket submission confirms that the ECOM Endobronchial Cardiac Output Monitor System is safe and effective for the intended use and is substantially equivalent to the predicate devices.