R1/2

SEP 19 2007

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92©

The assigned 510(k) number is: **K063735**

Name and Address of Applicant:

Presym, Inc.
15 Twelve Oaks Drive
Pleasanton, CA 94588-8210
Primary Contact: Tamim Hamid
510-714-0525

Preparation Date: July 17, 2007

Trade Name: Presym Tracheocardiogram System (TrCG)

Common Name: Cardiac Monitor

Product Code: DRT

Predicate Devices:

Vital Science Quantascope Model 103

Respironics Actiheart

VivoMetrics Lifeshirt

Nasiff Cardio-Card Management Stystem II

Description of new device:

The Presym TrCG is a non-invasive device intended to measure acceleration (displacement over time^2) of the trachea.

A tracheal motion sensor is implemented as a neck collar worn by the patient, connected electronically to a TrCG/ECG belt pack unit. The belt pack and associated PC software for signal acquisition and display utilizes the Nasiff Associates Cardio-Card Management System II (**K972795**). The monitor displays the TrCG waveform alongside the patient's ECG.

The TrCG system is provided non-sterile.

Intended Use / Indications for Use:
The Presym TrCG (Tracheocardiogram) is a non-invasive device intended to measure acceleration (displacement over time^2) of the trachea.

The trachea is mechanically linked to the heart and therefore its movement is directly related to that of the heart.

The TrCG displays are shown with the patient's ECG (electrocardiograph) and presented for the physician's consideration.

There are no set alarms or preset force limits.

Technological characteristics and comparison to predicate devices:
The Presym TrCG device has the same technological features and characteristics as the predicate devices. The intended use of the predicate devices and the TrCG device is similar.

Each of the technological characteristics features found in the Presym TrCG device is similar or identical to the specified predicate devices. Therefore, Presym, Inc. believes the claim of substantial equivalence to the commercially available predicate devices and the Presym TrCG device to be consistent with the 510(k) regulatory paradigm.

Performance / test data:
The Presym device complies with IEC 60601-1 and IEC 60601-1-2 as verified by independent test facilities. The TrCG device passed internal performance testing per internal company procedures.

Conclusions:
The Presym TrCG device has the same intended use as the predicate devices. The TrCG device also includes similar or identical technical features and characteristics as the predicate devices. Performance testing and validation exercises have produced results consistent with design input requirements. Therefore, the Presym TrCG device does not raise new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 19 2007

Presym, Inc.
c/o Mr. Tamim Hamid
President and CEO
15 Twelve Oaks Drive
Pleasanton, CA 94588-8210

Re: K063735
Trade/Device Name: Presym TrCG (Tracheocardiogram)
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II
Product Code: DRT
Dated: September 2, 2007
Received: September 5, 2007

Dear Mr. Hamid:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

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: **K063735**

Device Name: **Presym TrCG**

Indications for Use:

The Presym TrCG (Tracheocardiogram) is a non-invasive device intended to measure acceleration (displacement over time^2) of the trachea.

The trachea is mechanically linked to the heart and therefore its movement is directly related to that of the heart.

The TrCG displays are shown with the patient's ECG (electrocardiograph) and presented for the physician's consideration.

There are no set alarms or preset force limits.

Prescription Use __X____ (Part 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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ashley Boam for BDZ

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K063735