Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Philips Response To ResMed Update On Phase IV SERVE-HF Study Of Adaptive Servo-Ventilation (ASV) Therapy In Central Sleep Apnea And Chronic Heart Failure

Contact:
Consumer/Media:
Mario Fante
mario.fante@philips.com
603-560-9226

FOR IMMEDIATE RELEASE – June 11, 2015 – On May 15, 2015, Respironics, Inc., a Philips business, provided the following response to ResMed's Update on Phase IV SERVE-HF Study of Adaptive Servo-Ventilation (ASV) Therapy in Central Sleep Apnea and Chronic Heart Failure.

On May 13, 2015, ResMed issued a press release and a related Urgent Field Safety Notice. This report described a statistically significant 2.5 percent absolute increased annual risk of cardiovascular mortality for those randomized to a ResMed adaptive servo ventilation (ASV) therapy compared to the control group. In the patient population with LVEF $\leq$ 45%, 10.0 percent of the ASV group experienced a cardiovascular death each year compared to 7.5 percent of the control group, representing a 33.5 percent relative increased risk of cardiovascular mortality (HR=1.335, 95%CI=(1.070, 1.666), p-value= 0.010).

Philips is actively evaluating the information provided by ResMed and examining if this might impact the medical care of patients who use Philips BiPAP autoSV/BiPAP autoSV Advanced devices. As part of this ongoing investigation, we are working with

ResMed in order to better understand their study data. We are also evaluating post market surveillance data, public adverse event data and other published data to identify and assess other safety concerns that may be present.

Until we complete our investigation, based on the ResMed data, we strongly recommend clinicians adhere to the recommendations cautioning against the use of ASV therapy in patients with symptomatic chronic heart failure (NYHA 2-4) and reduced LVEF ≤45%, AND moderate to severe predominant central sleep apnea. Physicians prescribing ASV therapy are recommended to not place new patients in the at-risk population on the devices and to evaluate current patients; a discussion about whether to discontinue ASV therapy should occur if a current patient is found to be in the at-risk population. Therefore, as a precaution, physicians should assess individual risks before prescribing therapy with the Philips devices listed above for the at-risk patient population. No other patient populations have been identified as at-risk for adverse outcomes. Philips Respironics BiPAP autoSV/BiPAP autoSV Advanced devices are currently indicated to provide non-invasive ventilatory support to adult patients (>30 kg/66 lbs.) with obstructive sleep apnea and respiratory insufficiency caused by central and/or mixed apneas and periodic breathing. These devices are not approved or labeled for the treatment of heart failure.

We will continue to provide updates to the medical and service provider communities as additional information becomes available to ensure the continuous safe and effective use of our devices.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

###

RSS Feed for FDA Recalls Information [what's this?]

Page Last Updated: 06/11/2015
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)

Contact FDA

FDA Archive
Combination Products
Advisory Committees
Regulatory Information
Safety
Emergency Preparedness
International Programs
News & Events
Training & Continuing Education
Inspections & Compliance
Federal, State & Local Officials
Consumers
Health Professionals
Science & Research
Industry