Pharmacy_Subscriberlist@DCA

From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Wednesday, December 23, 2015 2:05 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Perseus A500 Anesthesia Workstation by Draeger: Class I Recall - Faulty Power Switch May Cause Device to Stop Working

Draeger is recalling the Perseus A500 anesthesia workstation because a faulty power switch may fail, causing the workstation to alarm and shut down unexpectedly. If this occurs, ventilation may fail and the patient may not receive either anesthesia or enough oxygen. This could cause patients to suffer serious adverse health consequences, including injury or death. The recall includes all Draeger Perseus A500 anesthesia workstations manufactured from June 1, 2013 to September 30, 2015 with distribution dates of February 1, 2015 to September 30, 2015. See the FDA Recall Notice for a link to a list of affected serial numbers.

The company has received one report of this issue occurring, with no injuries and no deaths.

BACKGROUND: The Draeger Perseus A500 Anesthesia Workstation provides anesthesia and breathing support for children and adults. This medical device is used in hospitals.

RECOMMENDATION: Draeger sent an urgent field safety notice to all customers with affected devices on November 10, 2015, informing them of this issue. The letter indicates that the power switch of affected workstations must be replaced. A Draeger service representative will contact customers to schedule a replacement, free of charge. Until the replacement takes place, Draeger recommends that users operate affected Perseus A500 workstations under continuous supervision. Customers with questions are instructed to call Draeger technical support: 1-800-543-5047.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form 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.

[12/23/2015 - Recall Notice - FDA]