Pharmacy_Subscriberlist@DCA

From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Friday, January 15, 2016 11:42 AM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Brainlab Cranial Image-Guided Surgery (IGS) System: Class I Recall - Navigation Inaccuracy

Brainlab is recalling the Cranial IGS System due to potential inaccuracies in the display by the navigation system compared to the patient anatomy. This could lead to inaccurate, ineffective medical procedures, and serious life-threatening injuries including death.

This recall includes the Brainlab Cranial IGS System and Brainlab Cranial Navigation Systems (all existing versions before Cranial 3.0), distribution dates: May 1996 to May 2015.

BACKGROUND: Brainlab Cranial IGS System shows the area of interest and the position of an instrument relative to the patient's anatomy to enable minimally invasive surgical procedures.

RECOMMENDATION: Brainlab notified customers of the issue on April 22, 2013 and issued an update on May 29, 2015. Customers should adhere to the Instructions for Use supplement document "Measures to Improve Cranial Navigation Accuracy" when using the affected product. Brainlab will provide customers with an updated software version and schedule the update installation starting in September 2015. Questions should be directed to Brainlab Customer Hotline: 1-800-597-5911 or by email support@Brainlab.com.

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

[01/15/2016 - Recall Notice - FDA]