



# California Medical Device Recall Information



## Recall Name

### Brainlab Recalls Brainlab Cranial IGS System Due to Navigation Inaccuracy

Recall Date	Product Description	Recalling Firm	Recall Reason
Initial: 04/22/13  Update: 05/29/15	<ul style="list-style-type: none"> <li>Brainlab Cranial IGS Systems</li> <li>Brainlab Cranial Navigation Systems (all existing versions before Cranial 3.0)</li> </ul>	<b>Brainlab</b> Germany	<i>Due to potential inaccuracies in the display by the navigation system compared to the patient anatomy.</i>
Recall Class	Product Identification	Distribution	Affected Dates
I	<b>ALL Brainlab Cranial IGS Systems</b>	CA, nationwide	Distribution Dates:  May 1996 to May 2015

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

<http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm481966.htm>