



California Medical Device Recall Information



Recall Name

ConvaTec Recalls Flexi-Seal CONTROL Fecal Management System Kit – Not Cleared for Marketing

Recall Date	Product Description	Recalling Firm	Recall Reason
4/29/14	Flexi-Seal CONTROL Fecal Management System Kit	ConvaTec, Inc. Greensboro, NC	<i>No FDA Clearance (510(k)) to legally market the device.</i> <i>Multiple reports of serious injuries associated with use of the device.</i>
Recall Class	Product Identification	Distribution	Affected Dates
I	Model Number: ICC 411107 SAP codes: 1704335 All Lots Recalled	CA , nationwide	Manufactured from: February 13, 2013 through April 14, 2014

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

<http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm402137.htm>