



California Medical Device Recall Information



Recall Name

**U.S. FDA Orders Custom Ultrasonics to
Recall Automated Endoscope Reprocessors
Due to Risk of Infection Transmission**

Recall Date	Product Description	Recalling Firm	Recall Reason
11/16/15	Automated Endoscope Reprocessors (AERs)	Custom Ultrasonics Ivyland, PA	<i>FDA identified violations that could result in an increased risk of infection transmission.</i>
Recall Class	Product Identification	Distribution	Affected Dates
I	<p>All Custom Ultrasonics AERs, including:</p> <ul style="list-style-type: none"> • System 83 Plus • System 83 Plus 2 • System 83 Plus 9 	Nationwide	All dates.

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

<http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm472940.htm>