California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Smiths Medical ASD, Inc. CADD-Solis HSPCA Pump, HPCA Ambulatory Infusion Pump, and VIP Ambulatory Infusion Pump

Recall Date	Product Description	Recalling Firm	Recall Reason
05/07/2025	CADD Solis HSPCA Pump	Smiths Medical ASD, Inc.	Pumps may experience Wireless Connection Modules intermittent connection alarms, which will interrupt an active infusion. Interruption or delay of therapy can lead to serious patient injury or death.
05/07/2025	CADD-Solis HPCA Ambulatory Infusion Pump CADD-Solis VIP Ambulatory Infusion Pump	Smiths Medical ASD, Inc.	Affected pumps may trigger an erroneous (false) Upstream Occlusion Alarm under certain conditions, which will interrupt an active infusion. Interruption or delay of therapy can lead to serious patient injury or death.
05/06/2025	CADD-Solis Infusion Pump Models CADD Solis VIP Ambulatory Infusion Pump Models	Smiths Medical ASD, Inc.	There is a potential for thermal damage in CADD-Solis and CADD-Solis VIP infusion pumps.

Recall Class	Product Identification	Distribution	Affected Dates
I	Affected CADD-Solis Software Versions: 4.0, 4.1, 4.2, 4.2.1, 4.3 UDI-DI: 4546027095675 - 35019517155130	83,833 units nationwide	April and prior
I	All CADD-Solis and CADD-Solis VIP Ambulatory Infusion Pumps UDI-DI: 10610586034787 - 35019517155130	185,975 units nationwide	April and prior
I	All serial numbers Model Number: 21-2111-0402-51 UDI-DI: 15019517154290 Model Number: 21-2112-0402-51 UDI-DI: 15019517154993 Model Number: 21-2112-0100-51 UDI-DI: 10610586039232 Model Number: 21-2111-0100-51 UDI-DI: 30610586039205 Model Number: 21-2101-51 UDI-DI: 10610586031854 Model Number: 21-2111-0300-00 UDI-DI: 10610586038792 Model Number: 21-2111-0402-78 UDI-DI: 15019517154887 Model Number: 21-2111-0100-00 UDI-DI: 10610586039195 Model Number: 21-2112-0300-00 UDI-DI: 10610586038822	313,676 units nationwide	April and prior

	Model Number: 21-2112-0402-78 UDI-DI: 15019517155013 Model Number: 21-2101-249 UDI-DI: 10610586034787 Model Number: 21-2102-51 UDI-DI: 10610586033933 Model Number: 21-2111-0300-231 UDI-DI: 10610586038785 Model Number: 21-2112-0401-78 UDI-DI: 15019517101034 Model Number: 21-2112-0400-51 UDI-DI: 10610586041051 Model Number: 21-2112-0300-50 UDI-DI: 10610586038860 Model Number: 21-2111-0300-00 UDI-DI: 10610586038792 Model Number: 21-2111-0100-00 UDI-DI: 10610586039195 Model Number: 21-2111-0100-51 UDI-DI: 30610586039205 Model Number: 21-2111-0100-50 UDI-DI: 10610586039256 Model Number: 21-2101-51 UDI-DI: 10610586031854 Model Number: 21-2112-0100-50 UDI-DI: 10610586039270 Model Number: 21-2101-00 UDI-DI: 35019517154904 Model Number: 21-2112-0400-01 UDI-DI: 10610586041822 Model Number: 21-2127-0105-01 UDI-DI: 15019517150292		

	Model Number: 21-2120-0105-01 UDI-DI: 15019517150001 Model Number: 21-2120-0103-01 UDI-DI: 15019517084368 Model Number: 21-2120-0102-51 UDI-DI: 10610586042829 Model Number: 21-2120-0104-01 UDI-DI: 15019517126587 Model Number: 21-2120-0103-51 UDI-DI: 15019517096378 Model Number: 21-2127-0104-01 UDI-DI: 15019517126600 Model Number: 21-2120-0105-00 UDI-DI: 15019517149999 Model Number: 21-2120-0103-78 UDI-DI: 15019517096392 Model Number: 21-2120-0102-78 UDI-DI: 10610586042836 Model Number: 21-2120-0104-231 UDI-DI: 15019517126617 Model Number: 21-2120-0102-249 UDI-DI: 10610586042843 Model Number: 21-2120-0103-249 UDI-DI: 15019517096385 Model Number: 21-2125-0104-01 UDI-DI: 15019517126594 Model Number: 21-2120-0102-249 UDI-DI: 10610586042843		

For additional information, please visit: FDA Website (HSPCA), FDA Website (HPCA), FDA Website (VIP), FDA Website (CADD-Solis), and FDA Website (CADD-Solis VIP).