California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

LivaNova USA, Inc. SenTiva Generators Part of the VNS Therapy System and with Microburst Stimulation

Recall Date	Product Description	Recalling Firm	Recall Reason
01/31/2025	SenTiva, REF: 1000; SenTiva Duo, REF: 1000-D; Generators Part of the VNS Therapy System. Used for Vagus Nerve Stimulation (VNS). SenTiva, REF: 1000C, Generators Part of the VNS Therapy System with Microburst Stimulation. Used for Vagus Nerve Stimulation (VNS).	LivaNova USA, Inc.	Vagus nerve stimulator generators may stop delivering stimulation due to an internal, mechanically activated component that may become stuck in a closed position, which may result in patients returning to baseline seizure frequency or depressive symptoms and in the longer term, patients may be required to undergo generator replacement surgery to replace their device.

Recall Class	Product Identification	Distribution	Affected Dates
II	REF/UDI-DI: 1000/05425025750405 1000-D/05425025750528 All Serial Numbers less than 500,000	REF 1000: 4604 units in California REF 1000-D: 104 units in California	December and prior

	UDI-DI: 05425025750405. All Serial Numbers less than 500,000.	REF 1000C: 0 units in California	

For additional information, please visit FDA Website (REF: 1000, 1000-D) and FDA Website (REF: 1000C).