California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Boston Scientific ACCOLADE Pacemakers And CRT-Ps Correction Recall

Recall Date	Product Description	Recalling Firm	Recall Reason
3/19/2026	The ACCOLADE family of implantable pacemakers and cardiac resynchronization therapy pacemakers (CRT-Ps) are devices used to provide dual chamber bradycardia pacing and adaptive rate pacing to detect and treat bradyarrhythmias.	**Boston Scientific Corporation** MA, USA	Boston Scientific initiated this correction to address unintended behaviors associated with the Brady SMR5 software update, including ZIP telemetry disablement, battery impedance issues, and potential early device replacement risks. The correction also expands the affected device scope to include all ACCOLADE CRT-P and DR-EL devices and implements the Brady SMR6 software/firmware update.

Recall Class	Product Identification	Distribution	Affected Dates
I	Affected ACCOLADE family pacemakers and CRT-Ps include multiple ESSENTIO, PROPONENT, ACCOLADE, ALTRUA 2, VALITUDE, and VISIONIST models listed in the FDA notice. Example model numbers include L300, L301, L310, L311, L321, L331, U125, U128, U225, U226,	US customers affected; units and specific distribution information were not provided in the FDA notice.	March 2026 and prior

	and U228. Example UDI-DIs include 00802526559150, 00802526559174, 00802526559204, 00802526559228, 00802526559242, and 00802526559266. Serial number ranges were not provided in the FDA notice and should be confirmed using Boston Scientific's device lookup tool.		

For additional information, please visit the FDA website