California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Abiomed, Inc. Recalls Impella RP Flex with SmartAssist

Recall Date	Product Description	Recalling Firm	Recall Reason
2/27/2026	Impella RP Flex with SmartAssist. Product Code: 1000323. Impella RP Flex with SmartAssist. Product Code: 1000323	Abiomed, Inc. Danvers, MA	Differential pressure (dP) sensor in Impella RP devices may malfunction, causing sensor values to drift.

Recall Class	Product Identification	Distribution	Affected Dates
I	Product Code: 1000323. UDI-DI: 00813502012811	4,496 Units Worldwide	January 2026 and prior

For additional information, please visit the FDA website