California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Abiomed, Inc. Impella RP Flex with SmartAssist

Recall Date	Product Description	Recalling Firm	Recall Reason
01/15/2025	Impella RP Flex with SmartAssist Product Number: 1000323	Abiomed, Inc.	Optical Sensors have been damaged due to physical interaction between the inlet and another device resulting in a Placement Signal Not Reliable (PSNR) alarm and loss of Central Venous (CV) Placement Signal, Pulmonary Artery (PA) Placement Signal & Pulmonary Artery Pulse Index (PAPi) metrics. Abiomed is reinforcing that there is a risk of potential interaction between the tip of guidewires, indwelling central venous lines or devices and inlet of the Impella pumps listed above during the insertion, manipulation, and removal of those devices. The interaction may result in optical sensor

			damage, temporary pump stop, or permanent pump stop.

Recall Class	Product Identification	Distribution	Affected Dates
I	Product Number: 1000323 UDI-DI: 00813502012811 Serial Numbers: 551121 - 407992A	2,364 units nationwide	December and prior

For additional information, please visit the FDA Website.