California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Leica Biosystems Melbourne Pty Ltd HistoCore Peloris 3

Recall Date	Product Description	Recalling Firm	Recall Reason
04/28/2025	HistoCore Peloris 3, Model/Catalog Number: 45.0005/45.7512.501 A11, Software Version: 3.4.0. The HistoCore PELORIS 3 Rapid Tissue Processor is a dual retort rapid tissue processor used to prepare tissue samples.	Leica Biosystems Melbourne Pty Ltd	There is a leakage issue associated with the tubing in the manifold of the instrument.

Recall Class	Product Identification	Distribution	Affected Dates
II	UDI-DI: 09349458004811; Serial Numbers: 45111117, 45111154, 45111155, 45111156, 45111157, 45111158, 45111159, 45111160, 45111161, 45111162, 45111164, 45111166, 45111167, 45111168, 45111169, 45111170, 45111171, 45111174, 45111175, 45111176, 45111177, 45111178, 45111179, 45111180, 45111181, 45111182, 45111183.	2 affected items distributed in California. Products were distributed to UCSF MT Zion Main Campus and Contra Costa Pathology Associates.	April 2025 and Prior

For additional information, please visit the FDA Website.