State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Medtronic Perfusion Systems Recalls Custom Perfusion Kits for Lack of Endotoxin Testing

Recall Date	Product Description	Recalling Firm	Recall Reason
10/12/2021	**Medtronic Custom Perfusion kits** CUSTOM PACK (Model BB10Q85R- TL7X09R3)	**Medtronic Perfusion Systems** Brooklyn Park, Minnesota	Product is labeled as non-pyrogenic but endotoxin testing was not performed.

Recall Class	Product Identification	Distribution	Affected Dates
II	Model BB10Q85R- TL7X09R3 (See link for individual serial no.)	23 Units in California	October 2021 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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