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 recalls Cardioblate Gemini Irrigated RF Surgical Ablation System

Recall Date	Product Description	Recalling Firm	Recall Reason
4/20/2022	**Medtronic Perfusion Systems** Reference No. CT-P60 D-2 02	**Medtronic Perfusion Systems** Brooklyn Park, Minnesota	Firm detected an increase in complaints related to fractured jaw tips of the Cardioblate Gemini-s.

Recall Class	Product Identification	Distribution	Affected Dates
II	ABLATION DEVICE 49260 PROCEDURE KIT Model 49260; GTIN: 00613994268051, Lot Numbers: 215G, 256E, 388C, 466C, 584D, 611A, 745F, 840C, 850C, 967C; GTIN: 00613994755643, Lot Numbers: 469C, 612A, 972C, 973C, GTIN: 00643169983120, Lot Numbers: 125E - 995D. CLAMP 49351 CARDIOBLATE GEMINI-S FT Model: 49351; GTIN: 00643169998117	49 Units in California	April 2022 and Prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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