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 TurboHawk Plus Directional Atherectomy System Recalled for Potential Tip Detachment

Recall Date	Product Description	Recalling Firm	Recall Reason
2/4/2022	**Medtronic TurboHawk Plus Directional Atherectomy System 6F** Multi-vessel, Catalog number THP-M. For use in peripheral vasculature.	**ev3 Inc.** Plymouth, Minnesota	The device has similarities in design to another device that had tip detachment and embolization.
2/4/2022	**Medtronic TurboHawk Plus Directional Atherectomy System 6F** Small Vessel, Catalog number THP-S. For use in peripheral vasculature.	**ev3 Inc.** Plymouth, Minnesota	Potential tip detachment.

Recall Class	Product Identification	Distribution	Affected Dates
I	**Medtronic TurboHawk Plus Directional Atherectomy System 6F (Multi-vessel)** GTIN 00763000402396	441 Devices Nationwide including California	February 2022 and prior
I	**Medtronic TurboHawk Plus Directional Atherectomy System 6F (Small-vessel)** GTIN 00763000402419	245 Devices Nationwide including California	February 2022 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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