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 Synergy Cranial and StealthStation S7 Cranial Software Due to Potential Risk of Inaccurate Biopsy Depth Gauge Cycle View

Recall Date	Product Description	Recalling Firm	Recall Reason
11/11/2021	**Stealthstation System w/ Stealthstation Cranial Software or SynergyCranial Software** Stealthstation Cranial Software 3.1.1,3.1.2,3.1.3 Synergy Cranial, Model: 9733763, and StealthStation Cranial, Model: 9735585	**Medtronic Navigation, Inc.** Louisville, Colorado	Cranial biopsy procedure software can enter a state where the biopsy depth gauge is no longer synchronized with the rest of the navigational information on the screen and may display an incorrect position of the biopsy needle, which may result in prolonged procedure, the need for additional surgical procedure, tissue injury.

Recall Class	Product Identification	Distribution	Affected Dates
I	9733763, Version: 2.2.8; 9735585, Versions: 3.1.1, 3.1.2, 3.1.3	100 Units in California	July 2020 - August 2020

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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