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 Navigation, Inc. StealthStation Cranial Software for Software Anomalies

Recall Date	Product Description	Recalling Firm	Recall Reason
6/14/2023	**StealthStation Cranial Software** Models: 9735585, 9735586 (kit), 9735587 (kit), used with StealthStation S7/i7 systems	**Medtronic Navigation, Inc.** Lafayette, CO	During non-axial/some axial exams, software anomalies occur during procedures affecting depth gauge graphic displays for cranial biopsy; causing displays to no longer synchronize with other navigational information showing inaccurate values, which may result in prolonged/additional procedure, tissue injury

Recall Class	Product Identification	Distribution	Affected Dates
I	**StealthStation Cranial Software** Model/UDI-DI; Software Version: 9735585/00763000631635, 9735586/00763000631765, 9735587/00763000631826; 3.1.4	746 Units Nationwide	April 2023 and Prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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