



Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

**Medtronic Navigation Recalls Stealthstation S8 Application Version 2.0 And 2.0.1 (Part 9735762)
 For Software Anomaly**

Recall Date	Product Description	Recalling Firm	Recall Reason
11/15/2023	<p>StealthStation S8 Application version 2.0 and 2.0.1 (Part 9735762)</p> <p>The StealthStation System, with StealthStation Cranial software, is intended as an aid for locating anatomical structures in either open or percutaneous neurosurgical procedures. The StealthStation FlexENT System, with StealthStation ENT software, is intended as an aid for locating anatomical structures in either open or percutaneous ENT procedures.</p>	<p>MEDTRONIC NAVIGATION, INC. Lafayette, Colorado</p>	<p>Due to a software anomaly which potentially could result in the surgical planning data shifting to an unintended location.</p>

Recall Class	Product Identification	Distribution	Affected Dates
I	<p>StealthStation S8 Application version 2.0 and 2.0.1 (Part 9735762)</p> <p>Model Number: 9735762 UDI-DI Code: 00763000532123 Software Versions 2.0 and 2.0.1 All systems with the impacted software version regardless of how it was purchased</p>	<p>5,240 Units Nationwide including California</p>	<p>27 September 2023 and prior</p>

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