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
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11/15/2023 | StealthStation S8 Application version 2.0 and 2.0.1 (Part 9735762)
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. | MEDTRONIC NAVIGATION, INC. Lafayette, Colorado | Due to a software anomaly which potentially could result in the surgical planning data shifting to an unintended location.

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

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE