

K212397 StealthStation S8 Cranial v2.0Dec 22, 2021
142 days to decisionK212397 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k212397/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Aug 2, 2021
Decision date	Dec 22, 2021
Days to decision	142 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Navigation
Location	Louisville, CO, US
Contact	Carey Brenner
510(k) history	9 submissions · 9 cleared · 2017-2025

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