

K242480 FLASH EVD System (10-0002)Dec 27, 2024
128 days to decisionK242480 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k242480/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Aug 21, 2024
Decision date	Dec 27, 2024
Days to decision	128 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	7D Surgical ULC
Location	Toronto, CA
Contact	Elena Marennny
510(k) history	1 submissions · 1 cleared · 2024-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242480/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026