FDA 510(k) Premarket Notification

K242480 FLASH EVD System (10-0002)

CLEARED

Dec 27, 2024
128 days to decision

K242480 · 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 Marenny
510(k) history	1 submissions · 1 cleared · 2024-2024