

K192945 7D Surgical System Cranial Biopsy and Ventricular Catheter Placement Application

Nov 27, 2019
40 days to decisionK192945 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k192945/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Oct 18, 2019
Decision date	Nov 27, 2019
Days to decision	40 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	7D Surgical, Inc.
Location	Toronto, CA
Contact	Daniel Zisind
510(k) history	9 submissions · 9 cleared · 2016-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192945/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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