FDA 510(k) Premarket Notification

K220072 Sinobot X1

CLEARED

Jun 18, 2023
524 days to decision

K220072 · Product code: **HAW** · Neurology
Source: https://www.510kdatabase.net/k220072/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Jan 10, 2022
Decision date	Jun 18, 2023
Days to decision	524 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Sinovation (Beijing) Medical Technology Co., Ltd.**
Location	Beijing, CN
Contact	Manman Xu
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Emergo Global Consulting, LLC**
Contact	Giselle Zhang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov