CLEARED

Feb 16, 2023
582 days to decision

K212194 Stryker Q Guidance System with Cranial Guidance Software, CranialMask Tracker and Microscope Tracker, Passive Optical Navigation Instruments, Mayfield Base with Articulating Arm, and Navigated Biopsy Needle, Electromagnetic Navigation Instruments, Precision Targeting System

K212194 · Product code: **HAW** · Neurology
Source: https://www.510kdatabase.net/k212194/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Jul 14, 2021
Decision date	Feb 16, 2023
Days to decision	582 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker Corporation**
Location	Malwah, NJ, US
Contact	Bryan K. Hann
Website	http://www.stryker.com/
510(k) history	81 submissions · 81 cleared · 2010-2023

Stryker Corporation is an American multinational medical technology company headquartered in Portage, Michigan. The company develops and markets surgical equipment, neurotechnology, orthopedic implants, and patient safety systems used globally across medical specialties. Stryker has received FDA 510(k) clearances from total submissions between 2010 and 2023. The company's cleared devices span orthopedic surgery, neurosurgery, general and plastic surgery, and ear, nose, and throat specialties. This regulatory record reflects the company's broad portfolio across surgical an...