

K183196 Stryker Navigation System with SpineMap Go Software Application, Fluoroscopy Trackers and Fluoroscopy Adapters, SpineMask Tracker

Feb 14, 2019
87 days to decision

K183196 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k183196/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Nov 19, 2018
Decision date	Feb 14, 2019
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Stryker Corporation
Location	Malwah, NJ, US
Contact	Andrea Wallen-Gerding
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...