

# K162929 Stryker Navigation System with CranialMap software application, Stryker CranialMap Planning software application, Stryker CranialMask Tracker

Feb 22, 2017  
126 days to decision

K162929 · Product code: **HAW** · Neurology  
Source: <https://www.510kdatabase.net/k162929/>

## SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Oct 19, 2016
Decision date	Feb 22, 2017
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

## APPLICANT

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Company	<b>Stryker Corporation</b>
Location	Malwah, NJ, US
Contact	Brittney M. Larsen
Website	<a href="http://www.stryker.com/">http://www.stryker.com/</a>
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...