

K150539 OASYS SystemMay 12, 2015
70 days to decisionK150539 · Product code: **NKG** · Orthopedic
Source: <https://www.510kdatabase.net/k150539/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Posterior Cervical Screw System (NKG)
Date received	Mar 3, 2015
Decision date	May 12, 2015
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Stryker Corporation
Location	Malwah, NJ, US
Contact	GARRY T. HAYECK
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...
