

K221728 Aviator® Anterior Cervical Plating (ACP) System, LITe® Plate System, DynaTran™ Anterior Cervical Plating (ACP) System, Reflex™ Hybrid ACP System, UniVise™ Spinous Process Fixation PlateOct 19, 2022
127 days to decisionK221728 · Product code: **KWQ** · Orthopedic
Source: <https://www.510kdatabase.net/k221728/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Jun 14, 2022
Decision date	Oct 19, 2022
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Stryker Corporation
Location	Malwah, NJ, US
Contact	Katie McNeil
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...

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