

K240690 STRUXXURE® MCS Anterior Cervical Plate SystemMar 22, 2024
9 days to decisionK240690 · Product code: **KWQ** · Orthopedic
Source: <https://www.510kdatabase.net/k240690/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Mar 13, 2024
Decision date	Mar 22, 2024
Days to decision	9 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nexxt Spine
Location	Noblesville, IN, US
Contact	Andy Elsbury
Website	https://nexxtspine.com
510(k) history	2 submissions · 2 cleared · 2024-2025

Nexxt Spine designs and manufactures spinal implants and instruments at its state-of-the-art facility in Noblesville, Indiana. The company specializes in 3D printed titanium interbodies, plating systems, pedicle screw systems, and related surgical instruments for spinal procedures. Since 2009, Nexxt Spine has maintained in-house manufacturing of 100% of implants and 95% of instruments. Nexxt Spine has received FDA 510(k) clearances from total submissions, with all submissions focused on Orthopedic devices. The company's regulatory activity spans 2024 to 2025, with the mos...
