

K211712 3° Anterior Cervical Plating System, Reliant Anterior Cervical Plating System, Unity Lumbosacral Fixation System, Hallmark Anterior Plate System, NewBridge Laminoplasty Fixation System, CETRA Anterior Cervical Plate SystemFeb 11, 2022
253 days to decisionK211712 · Product code: **KWQ** · Orthopedic
Source: <https://www.510kdatabase.net/k211712/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Jun 3, 2021
Decision date	Feb 11, 2022
Days to decision	253 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Orthofix US, LLC
Location	Lweisville, TX, US
Contact	Jacki Koch
510(k) history	4 submissions · 4 cleared · 2022-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211712/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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