

K211710 Ascent POCT System, Centurion POCT System, Spinal Fixation System (SFS), Firebird Spinal Fixation Systems: (Firebird Deformity Spinal Fixation System, Phoenix MIS Spinal Fixation System, Phoenix CDX MIS Spinal Fixation System, JANUS Midline Fixation Screws, Firebird NXG Spinal Fixation System, JANUS Fenestrated Screws), Connector System, FIREBIRD SI Fusion SystemJul 30, 2021
57 days to decisionK211710 · Product code: **NKG** · Orthopedic
Source: <https://www.510kdatabase.net/k211710/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Posterior Cervical Screw System (NKG)
Date received	Jun 3, 2021
Decision date	Jul 30, 2021
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Orthofix, Inc.
Location	Mckinney, TX, US
Contact	Jacki Koch
510(k) history	57 submissions · 57 cleared · 1996-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211710/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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