

K153169 PASS OCT Patient Specific RodsJan 29, 2016
88 days to decisionK153169 · Product code: **NKG** · Orthopedic
Source: <https://www.510kdatabase.net/k153169/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Posterior Cervical Screw System (NKG)
Date received	Nov 2, 2015
Decision date	Jan 29, 2016
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medicrea International
Location	Round Rock, TX, US
Contact	Davis Ryan
510(k) history	17 submissions · 16 cleared · 2011-2022

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