

**K213281 PASS LP™ Spinal System, CD Horizon™ Spinal System**Jan 5, 2022  
96 days to decisionK213281 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k213281/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Oct 1, 2021
Decision date	Jan 5, 2022
Days to decision	96 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medicrea International SA</b>
Location	Neyron, FR
Contact	Karine Trogneux
510(k) history	25 submissions · 25 cleared · 2015-2022

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