

K180980 ORTHROS™ Posterior Stabilization SystemOct 27, 2018
197 days to decisionK180980 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k180980/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Apr 13, 2018
Decision date	Oct 27, 2018
Days to decision	197 days
Third-party review	No
Summary / Statement	Summary
Other names	ORTHROS™ MIS Posterior Stabilization System

APPLICANT

Company	Camber Spine Technologies, LLC
Location	Wayne, PA, US
Contact	Tom Zamorski
510(k) history	6 submissions · 6 cleared · 2018-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180980/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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