

K223096 Dark Star Deformity Pedicle Screw SystemMay 26, 2023
238 days to decisionK223096 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k223096/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Sep 30, 2022
Decision date	May 26, 2023
Days to decision	238 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Republic Spine, LLC
Location	Pompano Beach, FL, US
Contact	James Doulgeris
510(k) history	7 submissions · 7 cleared · 2015-2023

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