

K191648 Mariner MIS Pedicle Screw SystemJul 19, 2019
29 days to decisionK191648 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k191648/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jun 20, 2019
Decision date	Jul 19, 2019
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary
Other names	SeaSpine Navigation System

APPLICANT

Company	SeaSpine Orthopedics Corporation
Location	Carlsbad, CA, US
Contact	Alicia McArthur
510(k) history	66 submissions · 66 cleared · 2016-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191648/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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