

K232566 NewPort Spinal SystemApr 19, 2024
239 days to decisionK232566 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k232566/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Aug 24, 2023
Decision date	Apr 19, 2024
Days to decision	239 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Daytona Small Stature Spinal System; Malibu Spinal System; Mariner Pedicle Screw Systems: Mariner Outrigger Revision System; Mariner MIS Pedicle Screw System; Mariner Deformity System; Mariner RDX System

APPLICANT

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

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