

K191757 EUROPA Pedicle Screw SystemJul 19, 2019
18 days to decisionK191757 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k191757/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jul 1, 2019
Decision date	Jul 19, 2019
Days to decision	18 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	MiRus, LLC
Location	Marietta, GA, US
Contact	Jordan Bauman
Website	https://www.mirusmed.com
510(k) history	24 submissions · 24 cleared · 2018-2026

MiRus, LLC is a medical device company based in Marietta, Georgia. The company develops innovative orthopedic implants and surgical solutions. MiRus has received FDA 510(k) clearances from total submissions since its first clearance in 2018. The company specializes exclusively in orthopedic devices, with a focus on spinal fusion systems, interbody fusion devices, and osteotomy solutions. Recent clearances include posterior cervical fusion systems, lumbar plating systems, and expandable wedge osteotomy devices. The company remains actively engaged in FDA submissions, with ...