FDA 510(k) Premarket Notification

K192268 Europa Pedicle Screw System

CLEARED

Oct 22, 2019
62 days to decision

K192268 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k192268/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Aug 21, 2019
Decision date	Oct 22, 2019
Days to decision	62 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 ...