FDA 510(k) Premarket Notification

K242516 EUROPA™ Posterior Cervical Fusion System

CLEARED

Nov 19, 2024
88 days to decision

K242516 · Product code: **NKG** · Orthopedic
Source: https://www.510kdatabase.net/k242516/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Posterior Cervical Screw System (NKG)
Date received	Aug 23, 2024
Decision date	Nov 19, 2024
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**MiRus, LLC**
Location	Marietta, GA, US
Contact	Anuradha Nagulapati
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 ...