FDA 510(k) Premarket Notification

K210800 IO Expandable Lumbar Interbody Fusion System

CLEARED

Aug 20, 2021
157 days to decision

K210800 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k210800/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Mar 16, 2021
Decision date	Aug 20, 2021
Days to decision	157 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 ...