CLEARED

K182920 MiRus™ Lumbar Interbody Fusion System consisting of CALLISTO™ PEEK Posterior Lumbar Interbody Fusion (PLIF)

Mar 13, 2019
145 days to decision

K182920 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k182920/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Oct 19, 2018
Decision date	Mar 13, 2019
Days to decision	145 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	HYPERION™ PEEK Transforaminal Lumbar Interbody Fusion (TLIF); CALPYSO™ PEEK Lateral Lumbar Interbody Fusion (LLIF); ANTARES™ PEEK Anterior Lumbar Interbody Fusion (ALIF)

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 ...