

**K232481 RIGEL™ 3DR Anterior Cervical Corpectomy System**Oct 13, 2023  
58 days to decisionK232481 · Product code: **PLR** · Orthopedic  
Source: <https://www.510kdatabase.net/k232481/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinal Vertebral Body Replacement Device - Cervical (PLR)
Date received	Aug 16, 2023
Decision date	Oct 13, 2023
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>MiRus, LLC</b>
Location	Marietta, GA, US
Contact	Jordan Bauman
Website	<a href="https://www.mirusmed.com">https://www.mirusmed.com</a>
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 ...