

**K200685 RIGEL 3DR Anterior Cervical Interbody Fusion System**Jun 11, 2020  
87 days to decisionK200685 · Product code: **ODP** · Orthopedic  
Source: <https://www.510kdatabase.net/k200685/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Mar 16, 2020
Decision date	Jun 11, 2020
Days to decision	87 days
Third-party review	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 ...

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