

**K201519 PROFEMUR® GLADIATOR® Cemented Classic Stem**Dec 10, 2020  
185 days to decisionK201519 · Product code: **JDI** · Orthopedic  
Source: <https://www.510kdatabase.net/k201519/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Cemented (JDI)
Date received	Jun 8, 2020
Decision date	Dec 10, 2020
Days to decision	185 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Microport Orthopedics, Inc.</b>
Location	Arlington, TN, US
Contact	Kristen Russell
510(k) history	37 submissions · 37 cleared · 2014-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201519/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 15, 2026