

**K213129 Restoration Modular 115mm Conical Distal Stem**Dec 21, 2021  
85 days to decisionK213129 · Product code: **LZO** · Orthopedic  
Source: <https://www.510kdatabase.net/k213129/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/ceramic/polymer, Cemented Or Non-porous, Uncemented (LZO)
Date received	Sep 27, 2021
Decision date	Dec 21, 2021
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Howmedica Osteonics Corp., Db a Stryker Orthopaedics</b>
Location	Malwah, NJ, US
Contact	Allison Byrne
Website	<a href="https://www.stryker.com">https://www.stryker.com</a>
510(k) history	31 submissions · 31 cleared · 2010-2026

Howmedica Osteonics Corp., Db a Stryker Orthopaedics is a medical device manufacturer based in Malwah, US. The company operates as part of Stryker, a global medical technology leader. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2010. 97% of submissions focus on Orthopedic devices, including joint replacement systems, knee implants, and hip components. The latest clearance in 2026 demonstrates continued regulatory activity and product innovation. Recent cleared devices include the Triathlon® Total Knee System with multi...

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Device record: <https://www.510kdatabase.net/k213129/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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