

**K193545 Corin Optimized Positioning System (OPS) Femoral**Aug 4, 2020  
228 days to decisionK193545 · Product code: **LZO** · Orthopedic  
Source: <https://www.510kdatabase.net/k193545/>**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	Dec 20, 2019
Decision date	Aug 4, 2020
Days to decision	228 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Corin USA</b>
Location	Tampa, FL, US
Contact	Lucinda Gerber
510(k) history	57 submissions · 57 cleared · 1996-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Corin (Australia)</b>
Contact	Crissy Tomarelli

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k193545/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 27, 2026