

K181598 Prime E-CLASS XLPE LinerSep 14, 2018
88 days to decisionK181598 · Product code: **LZO** · Orthopedic
Source: <https://www.510kdatabase.net/k181598/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/ceramic/polymer, Cemented Or Non-porous, Uncemented (LZO)
Date received	Jun 18, 2018
Decision date	Sep 14, 2018
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Microport Orthopedics, Inc.
Location	Arlington, TN, US
Contact	Sarah Evonne Stroupe
510(k) history	37 submissions · 37 cleared · 2014-2025

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