

K220483 Platform® Acetabular SystemSep 23, 2022
217 days to decisionK220483 · Product code: **LZO** · Orthopedic
Source: <https://www.510kdatabase.net/k220483/>**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	Feb 18, 2022
Decision date	Sep 23, 2022
Days to decision	217 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Total Joint Orthopedics, Inc.
Location	Sunnyvale, CA, US
Contact	Chris Weaber
510(k) history	21 submissions · 21 cleared · 2010-2022

REGULATORY CONSULTANT

Consulting firm	Mcra, LLC
Contact	Holly Rhodes

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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