

K230876 RI.KNEE Adjustable Tibia Cut GuideJun 27, 2023
89 days to decisionK230876 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k230876/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Mar 30, 2023
Decision date	Jun 27, 2023
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Enztec Limited
Location	Middleton, NZ
Contact	Breanna Crowther
510(k) history	5 submissions · 5 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	Empirical Technologies
Contact	Nathan Wright

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

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