

K222097 OLYMPIC Deformity Band SystemMay 4, 2023
290 days to decisionK222097 · Product code: **OWI** · Orthopedic
Source: <https://www.510kdatabase.net/k222097/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Fixation Cerclage, Sublaminar (OWI)
Date received	Jul 18, 2022
Decision date	May 4, 2023
Days to decision	290 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Astura Medical
Location	Carlsbad, CA, US
Contact	Parker Kelch
510(k) history	21 submissions · 21 cleared · 2016-2026

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