

K200097 Response BandLoc Spinal FixationMar 16, 2020
60 days to decisionK200097 · Product code: **OWI** · Orthopedic
Source: <https://www.510kdatabase.net/k200097/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Fixation Cerclage, Sublaminar (OWI)
Date received	Jan 16, 2020
Decision date	Mar 16, 2020
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	OrthoPediatics Corp.
Location	Warsaw, IN, US
Contact	Jackie Jaskula
Website	https://www.orthopediatrics.com
510(k) history	40 submissions · 38 cleared · 2008-2026

OrthoPediatics Corp. is a pediatric orthopedic medical device company focused exclusively on children's orthopedic care. Based in Warsaw, Indiana, the company designs and manufactures implants and surgical systems for pediatric trauma, deformity correction, scoliosis, and sports medicine applications. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2008. 100% of submissions fall within the Orthopedic device category. The latest clearance in 2026 reflects continued regulatory activity and product innovation in pediatric o...

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