

K082375 ORTHOPEDIATRICS PEDIFLEX FLEXIBLE NAIL SYSTEMOct 17, 2008
60 days to decisionK082375 · Product code: HTY · Orthopedic
Source: <https://www.510kdatabase.net/k082375/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pin, Fixation, Smooth (HTY)
Date received	Aug 18, 2008
Decision date	Oct 17, 2008
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

OrthoPediatrics 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...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k082375/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 19, 2026