

**K200518 Pitkar External Fixation System - Rail Mechanism**Jul 29, 2020  
149 days to decisionK200518 · Product code: **KTT** · Orthopedic  
Source: <https://www.510kdatabase.net/k200518/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Nail/blade/plate Combination, Multiple Component (KTT)
Date received	Mar 2, 2020
Decision date	Jul 29, 2020
Days to decision	149 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>S.H.Pitkar Orthotools Pvt. , Ltd.</b>
Location	Pune, IN
Contact	Vivek Mangalwedhekar
510(k) history	5 submissions · 5 cleared · 2019-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200518/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026