

**K230623 KITE Distal Fibula Kit**Sep 1, 2023  
179 days to decisionK230623 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k230623/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Mar 6, 2023
Decision date	Sep 1, 2023
Days to decision	179 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Intrauma S.P.A</b>
Location	Rivoli (To), IT
Contact	Piero Costa
510(k) history	3 submissions · 3 cleared · 2021-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230623/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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