

**K201147 Elos® Intramedullary Nailing System**Jul 19, 2021  
446 days to decisionK201147 · Product code: **HSB** · Orthopedic  
Source: <https://www.510kdatabase.net/k201147/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Apr 29, 2020
Decision date	Jul 19, 2021
Days to decision	446 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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mcra, LLC</b>
Contact	Hollace Saas Rhodes

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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