

**K192653 Perseus**Sep 9, 2020  
351 days to decisionK192653 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k192653/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Sep 24, 2019
Decision date	Sep 9, 2020
Days to decision	351 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Orthokey Italia S.R.L.</b>
Location	Carrara, IT
Contact	Cristiano Paggetti
510(k) history	1 submissions · 1 cleared · 2020-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Isemed S.R.L.</b>
Contact	Guido Bonapace

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192653/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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