

**K202956 Erisma LP Navigated Instruments**Feb 26, 2021  
149 days to decisionK202956 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k202956/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Sep 30, 2020
Decision date	Feb 26, 2021
Days to decision	149 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Clariance, Sas</b>
Location	Beaurains, FR
Contact	Fadwa Bahr
510(k) history	11 submissions · 11 cleared · 2016-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Msquared Associates, Inc.</b>
Contact	Jennifer A. Daudelin

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/k202956/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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