

**K221028 SURGIVISIO Device**Jul 6, 2022  
90 days to decisionK221028 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k221028/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Apr 7, 2022
Decision date	Jul 6, 2022
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ecential Robotics</b>
Location	Gieres, FR
Contact	Sarah Lefevre-Billard
510(k) history	6 submissions · 6 cleared · 2022-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221028/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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