

**K223351 Naviswiss Knee**Jan 31, 2023  
90 days to decisionK223351 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k223351/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Nov 2, 2022
Decision date	Jan 31, 2023
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>Naviswiss AG</b>
Location	Brugg, CH
Contact	Domenico Romeo
510(k) history	3 submissions · 3 cleared · 2020-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Confinis AG</b>
Contact	Frederike Bruhschwein-Mandic

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/k223351/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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