

**K211429 NAVIPLAN - CT Planning Software for Total Hip Replacement**Oct 5, 2021  
151 days to decisionK211429 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k211429/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	May 7, 2021
Decision date	Oct 5, 2021
Days to decision	151 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	Jan Stifter
510(k) history	3 submissions · 3 cleared · 2020-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Confinis AG</b>
Contact	Stefano Adami

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211429/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 26, 2026