

**K223441 SpaceFlex Acetabular Cup**Mar 23, 2023  
129 days to decisionK223441 · Product code: **KWY** · Orthopedic  
Source: <https://www.510kdatabase.net/k223441/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Hemi-, Femoral, Metal/polymer, Cemented Or Uncemented (KWY)
Date received	Nov 14, 2022
Decision date	Mar 23, 2023
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>G21, S.R.L.</b>
Location	San Possidonio, IT
Contact	Filippo Foroni
510(k) history	12 submissions · 12 cleared · 2015-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223441/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026