

**K240200 HYDROS Robotic System**Aug 20, 2024  
208 days to decisionK240200 · Product code: **PZP** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k240200/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluid Jet Removal System (PZP)
Date received	Jan 25, 2024
Decision date	Aug 20, 2024
Days to decision	208 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	HYDROS TRUS Probe; HYDROS Handpiece

**APPLICANT**

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Company	<b>Procept Biorobotics</b>
Location	San Jose, CA, US
Contact	Sara Muddell
510(k) history	3 submissions · 3 cleared · 2024-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k240200/> 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 13, 2026