

K251082 HYDROS Robotic System (HY1000)Oct 10, 2025
184 days to decisionK251082 · Product code: **PZP** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k251082/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluid Jet Removal System (PZP)
Date received	Apr 9, 2025
Decision date	Oct 10, 2025
Days to decision	184 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	HYDROS Handpiece (HH1000); HYDROS TRUS Probe (HU1000)

APPLICANT

Company	Procept Biorobotics
Location	San Jose, CA, US
Contact	Bijesh Chandran
510(k) history	3 submissions · 3 cleared · 2024-2025

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