

K260723 HYDROS Robotic System (HY1000)

Jul 9, 2026
126 days to decision

K260723 · Product code: **PZP** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k260723/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluid Jet Removal System (PZP)
Date received	Mar 5, 2026
Decision date	Jul 9, 2026
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary
Other names	HYDROS Handpiece (HH1000);HYDROS TRUS Probe (HU1000)

APPLICANT

Company	Procept Biorobotics
Location	San Jose, CA, US
Contact	Ankur Kaushal
510(k) history	5 submissions · 5 cleared · 2024-2026

510k Database - www.510kdatabase.net
Device record: <https://www.510kdatabase.net/k260723/> Data sourced from FDA 510(k) public records (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. - Generated August 20, 2026