

**K231024 AquaBeam Robotic System**Aug 30, 2023  
141 days to decisionK231024 · Product code: **PZP** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k231024/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluid Jet Removal System (PZP)
Date received	Apr 11, 2023
Decision date	Aug 30, 2023
Days to decision	141 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Procept Biorobotics, Corporation</b>
Location	Redwood City, CA, US
Contact	Sara Muddell
510(k) history	4 submissions · 3 cleared · 2017-2023

**CLINICAL EVIDENCE - NCT02505919****Waterjet Ablation Therapy for Endoscopic Resection of Prostate Tissue (WATER)**

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Status	Completed
Enrollment	184 patients (actual)
Study sites	17 sites
Condition studied	Benign Prostatic Hyperplasia (BPH)
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Double blind
Completion date	Dec 16, 2021
Sponsor	PROCEPT BioRobotics (Industry)

**Primary outcome****Proportion of Subjects With Adverse Events (Clavien-Dindo Grading System Grade 2 or Higher or Any Grade 1 Event Resulting in Persistent Disability)**Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT02505919](https://clinicaltrials.gov/study/NCT02505919)