

**K233778 Single Use Suction Access Ureteroscope (PU400A, PU411A), Single Use Flexible Video Ureteroscope (PU3033H, PU3033AH)**Jul 16, 2024  
232 days to decisionK233778 · Product code: **FGB** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k233778/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	Nov 27, 2023
Decision date	Jul 16, 2024
Days to decision	232 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zhuhai Pusen Medical Technology Co., Ltd.</b>
Location	Zhuhai, CN
Contact	Changshen Wang
510(k) history	7 submissions · 7 cleared · 2017-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233778/> 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 14, 2026