

**K220781 ARMADA Ureteral Dilator Set, ARMADA Nottingham One Step Dilator, ARMADA Amplatz Renal Dilator Sets, ARMADA Renal Dilator, Glider Amplatz Sheath, ARMADA Renal Dilator with Amplatz Sheath, Fascial Dilator Set, Introducer Sheath, Introducer Catheter**May 5, 2023  
414 days to decisionK220781 · Product code: **EZN** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k220781/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Catheter, Ureteral (EZN)
Date received	Mar 17, 2022
Decision date	May 5, 2023
Days to decision	414 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Allwin Medical Devices, Inc.</b>
Location	Anaheim, CA, US
Contact	Digish Mehta
510(k) history	7 submissions · 6 cleared · 2019-2023

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