

**K213185 ImaJin Silicone double loop ureteral stent kits, ImaJin  
Pyelostent Silicone double loop ureteral stent kits, ImaJin  
Stenostent Silicone double loop ureteral stent kits**Jun 8, 2022  
252 days to decisionK213185 · Product code: **FAD** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k213185/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Stent, Ureteral (FAD)
Date received	Sep 29, 2021
Decision date	Jun 8, 2022
Days to decision	252 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Coloplast Corp.</b>
Location	Marietta, GA, US
Contact	Gayatri Ghadge
510(k) history	54 submissions · 47 cleared · 1985-2025

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