

**K190312 Dornier Ureteral Stent**Nov 15, 2019  
276 days to decisionK190312 · Product code: **FAD** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k190312/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stent, Ureteral (FAD)
Date received	Feb 12, 2019
Decision date	Nov 15, 2019
Days to decision	276 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dornier Medtech America, Inc.</b>
Location	Marietta, GA, US
Contact	John Hoffer
510(k) history	40 submissions · 40 cleared · 1990-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190312/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026