

K180053 Sof-Flex Ureteral Stent SetSep 13, 2018
248 days to decisionK180053 · Product code: **FAD** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k180053/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stent, Ureteral (FAD)
Date received	Jan 8, 2018
Decision date	Sep 13, 2018
Days to decision	248 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cook Incorporated
Location	Bloomington, IN, US
Contact	Minjin Choi
510(k) history	175 submissions · 153 cleared · 2006-2024

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