

K181431 Laser Ureteral CatheterJul 30, 2018
59 days to decisionK181431 · Product code: **GEX** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k181431/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 1, 2018
Decision date	Jul 30, 2018
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181431/> Data sourced from FDA 510(k) public records (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. - Generated May 30, 2026