FDA 510(k) Premarket Notification

K162109 Kwart Retro-Inject Ureteral Stent

CLEARED

Jun 7, 2017
313 days to decision

K162109 · Product code: **FAD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k162109/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stent, Ureteral (FAD)
Date received	Jul 29, 2016
Decision date	Jun 7, 2017
Days to decision	313 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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