FDA 510(k) Premarket Notification

K180057 VORTEK URETERAL DOUBLE LOOP STENT

CLEARED

Mar 9, 2018
60 days to decision

K180057 · Product code: **FAD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k180057/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stent, Ureteral (FAD)
Date received	Jan 8, 2018
Decision date	Mar 9, 2018
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Coloplast Corp.**
Location	Marietta, GA, US
Contact	Cori Ragan
510(k) history	54 submissions · 47 cleared · 1985-2025