FDA 510(k) Premarket Notification

K201436 Vortek Single Loop Ureteral Stent

CLEARED

Feb 25, 2021
269 days to decision

K201436 · Product code: **FAD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k201436/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stent, Ureteral (FAD)
Date received	Jun 1, 2020
Decision date	Feb 25, 2021
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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