FDA 510(k) Premarket Notification

K161277 ConvertX Nephroureteral Stent System

CLEARED

Nov 22, 2016
200 days to decision

K161277 · Product code: **FAD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k161277/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stent, Ureteral (FAD)
Date received	May 6, 2016
Decision date	Nov 22, 2016
Days to decision	200 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Brightwater Medical**
Location	Dunlap, IL, US
Contact	BOB SMOUSE
510(k) history	2 submissions · 2 cleared · 2016-2019