FDA 510(k) Premarket Notification

K190612 EQUINOX Balloon Dilatation Catheter

CLEARED

Dec 6, 2019
270 days to decision

K190612 · Product code: **EZN** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k190612/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Catheter, Ureteral (EZN)
Date received	Mar 11, 2019
Decision date	Dec 6, 2019
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Dornier Medtech America, Inc.**
Location	Marietta, GA, US
Contact	John Hoffer
510(k) history	40 submissions · 40 cleared · 1990-2023