

K190612 EQUINOX Balloon Dilatation CatheterDec 6, 2019
270 days to decisionK190612 · Product code: **EZN** · Gastroenterology & UrologySource: <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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190612/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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