

K201815 Dornier MAGELLAN Ureteral Access SheathNov 20, 2020
142 days to decisionK201815 · Product code: **FED** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k201815/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Jul 1, 2020
Decision date	Nov 20, 2020
Days to decision	142 days
Third-party review	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

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