

K160437 PleurX Peritoneal Catheter SystemNov 3, 2016
260 days to decisionK160437 · Product code: **PNG** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k160437/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - KD
Submission type	Traditional
Device classification	Peritoneal, Drainage Catheter For Refractory Ascites, Long-term Indwelling (PNG)
Date received	Feb 17, 2016
Decision date	Nov 3, 2016
Days to decision	260 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Care Fusion
Location	Waukegan, IL, US
Contact	Tamara Brey
510(k) history	34 submissions · 29 cleared · 2010-2024

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