

K201155 PleurX Peritoneal Catheter SystemOct 21, 2020
174 days to decisionK201155 · Product code: **PNG** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k201155/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Peritoneal, Drainage Catheter For Refractory Ascites, Long-term Indwelling (PNG)
Date received	Apr 30, 2020
Decision date	Oct 21, 2020
Days to decision	174 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201155/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026