

K221779 ASEPT Peritoneal Drainage SystemMay 2, 2023
315 days to decisionK221779 · Product code: **PNG** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k221779/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Peritoneal, Drainage Catheter For Refractory Ascites, Long-term Indwelling (PNG)
Date received	Jun 21, 2022
Decision date	May 2, 2023
Days to decision	315 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pfm Medical, Inc.
Location	Oceanside, CA, US
Contact	Jessica Jho
510(k) history	20 submissions · 17 cleared · 2004-2025

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