

K230319 Passio Pump Drainage SystemNov 24, 2023
291 days to decisionK230319 · Product code: **PNG** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k230319/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Peritoneal, Drainage Catheter For Refractory Ascites, Long-term Indwelling (PNG)
Date received	Feb 6, 2023
Decision date	Nov 24, 2023
Days to decision	291 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Bearpac Medical
Location	Moultonborough, NH, US
Contact	Jay Zimmerman
510(k) history	3 submissions · 2 cleared · 2019-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230319/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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