FDA 510(k) Premarket Notification

CLEARED

K231096 Automatic Continuous Effusion Shunt (ACES) System ACES System

Aug 18, 2023
122 days to decision

K231096 · Product code: **KPM** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k231096/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shunt, Peritoneal (KPM)
Date received	Apr 18, 2023
Decision date	Aug 18, 2023
Days to decision	122 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Pleural Dynamics, Inc.**
Location	Wayzata, MN, US
Contact	Martin Mayse
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Ostendorf Consulting, LLC**
Contact	Joseph Ostendorf

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov