FDA 510(k) Premarket Notification

CLEARED

K212658 CloudCath Peritoneal Dialysis Drain Set Monitoring System

Feb 9, 2022
170 days to decision

K212658 · Product code: **FKX** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k212658/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Peritoneal, Automatic Delivery (FKX)
Date received	Aug 23, 2021
Decision date	Feb 9, 2022
Days to decision	170 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Cloudcath**
Location	San Francisco, CA, US
Contact	Brian Fisher
510(k) history	1 submissions · 1 cleared · 2022-2022

CLINICAL EVIDENCE - NCT04515498

A Prospective Clinical Study of the CloudCath System During In-home Peritoneal Dialysis

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	243 patients (actual)
Study sites	1 site
Condition studied	Peritoneal Dialysis-associated Peritonitis
Study type	Observational
Completion date	Mar 31, 2023
Sponsor	CloudCath (Industry)

Primary outcome

Time of peritonitis detection (vs lab measures)

Secondary outcome

Time of peritonitis detection (vs clinical measures)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04515498