

**K250523 Archimedes Pro Automated Peritoneal Dialysis Cyclers
(3014-00000-1)**Oct 2, 2025
223 days to decisionK250523 · Product code: **FKX** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k250523/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Peritoneal, Automatic Delivery (FKX)
Date received	Feb 21, 2025
Decision date	Oct 2, 2025
Days to decision	223 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Archimedes Standard Automated Peritoneal Dialysis Cyclers (3014-00000-3); Archimedes Pro Disposable Tubing Set (3014-50000-1); Archimedes Standard Disposable Tubing Set (3014-50000-3); Archimedes Pro Plus Disposable Tubing Set (3014-50000-5)

APPLICANT

Company	Simergent, LLC
Location	Oklahoma City, OK, US
Contact	Steve Lindo
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250523/> 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 13, 2026