

K243371 Byonyks X-1 APD CyclorMay 16, 2025
198 days to decisionK243371 · Product code: **FKX** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k243371/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Peritoneal, Automatic Delivery (FKX)
Date received	Oct 30, 2024
Decision date	May 16, 2025
Days to decision	198 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Byonyks Automated PD Set DS-1

APPLICANT

Company	Byonyks Pvt, Ltd.
Location	Lahore, PK
Contact	Eric Flachbart
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243371/> 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