

**K220935 Digital Dialysis Clinic - Intelligent Dialysis Assistant (IDA) with Medical Supervision Portal and IDA Smartphone App**Dec 29, 2022  
273 days to decisionK220935 · Product code: **FKX** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k220935/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Peritoneal, Automatic Delivery (FKX)
Date received	Mar 31, 2022
Decision date	Dec 29, 2022
Days to decision	273 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Iren-Medical, Ltd.</b>
Location	Or Aquiva, IL
Contact	Hezkiah Tsoory
510(k) history	1 submissions · 1 cleared · 2022-2022

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Insight Medical Consulting, LLC</b>
Contact	Wanda Carpinella

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

---

510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k220935/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 25, 2026