

**K253412 Tablo Hemodialysis System (PN-0008000,
PN-0006000U)**Jan 26, 2026
118 days to decisionK253412 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k253412/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI) |
| Date received | Sep 30, 2025 |
| Decision date | Jan 26, 2026 |
| Days to decision | 118 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Outset Medical, Inc. |
| Location | San Jose, CA, US |
| Contact | Dinamarie Stefani |
| 510(k) history | 9 submissions · 9 cleared · 2016-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253412/> 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 14, 2026