

K093964 VENOFER PUMPJul 9, 2010
197 days to decisionK093964 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k093964/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Abbreviated |
| Device classification | Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI) |
| Date received | Dec 24, 2009 |
| Decision date | Jul 9, 2010 |
| Days to decision | 197 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Renal Solutions, Inc. |
| Location | Apollo, PA, US |
| Contact | DAVID VANELLA |
| 510(k) history | 9 submissions · 9 cleared · 2003-2013 |

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