

**K013733 SYSTEM 100**Jun 3, 2002  
206 days to decisionK013733 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k013733/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Traditional   |
| Device classification | Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI) |
| Date received         | Nov 9, 2001   |
| Decision date         | Jun 3, 2002   |
| Days to decision      | 206 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |
| Other names           | S-100 ULTRAFILTRATION CONSOLE; BDT 500 ULTRAFILTRATION SET                |

**APPLICANT**

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|----------------|---|
| Company        | <b>Chf Solutions, Inc.</b>              |
| Location       | Washington, DC, US                      |
| Contact        | DIANNA THOMSEN                          |
| 510(k) history | 13 submissions · 13 cleared · 2002-2020 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k013733/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 30, 2026