

**K933883 GAMBRO FH 66 D HEMOFILTER**Mar 13, 1995  
580 days to decisionK933883 · Product code: **KDI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k933883/>**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         | Aug 10, 1993  |
| Decision date         | Mar 13, 1995  |
| Days to decision      | 580 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Cobe Renal Care, Inc.</b>            |
| Location       | Lakewood, CO, US                        |
| Contact        | JEFFREY R SHIDEMAN                      |
| 510(k) history | 14 submissions · 14 cleared · 1994-1997 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k933883/> 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