FDA 510(k) Premarket Notification

# K050609 AQUADEX SYSTEM

**CLEARED**

Nov 9, 2005
244 days to decision

K050609 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k050609/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI) |
| Date received | Mar 10, 2005 |
| Decision date | Nov 9, 2005 |
| Days to decision | 244 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Chf Solutions, Inc.** |
| Location | Washington, DC, US |
| Contact | CHRIS SCAVOTTO |
| 510(k) history | 13 submissions · 13 cleared · 2002-2020 |