

K192756 Aquadex FlexFlow System 2.0Feb 24, 2020
147 days to decisionK192756 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k192756/>**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, 2019
Decision date	Feb 24, 2020
Days to decision	147 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Chf Solutions, Inc.
Location	Washington, DC, US
Contact	Dawn Li
510(k) history	13 submissions · 13 cleared · 2002-2020

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