

K230632 VersiHD with GuideMe softwareAug 11, 2023
157 days to decisionK230632 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k230632/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Mar 7, 2023
Decision date	Aug 11, 2023
Days to decision	157 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nxstage Medical, Inc.
Location	Tewksburt, MA, US
Contact	Denise Oppermann
510(k) history	51 submissions · 51 cleared · 2001-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230632/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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