FDA 510(k) Premarket Notification

K230632 VersiHD with GuideMe software

CLEARED

Aug 11, 2023
157 days to decision

K230632 · Product code: **KDI** · Gastroenterology & Urology
Source: 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