

K080919 NXSTAGE PUREFLOW SLOct 15, 2008
197 days to decisionK080919 · Product code: **FKR** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k080919/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Subsystem, Proportioning (FKR)
Date received	Apr 1, 2008
Decision date	Oct 15, 2008
Days to decision	197 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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