CLEARED

K134019 MEDISYSTEMS ONESITE DUAL LUMEN NEEDLE WITH MASTERGUARD ANTI-STICK NEEDLE PROTECTOR, MEDISYSTEMS ONESITE DUAL LUMEN BUTTO

Sep 11, 2014
255 days to decision

K134019 · Product code: **FIE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k134019/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Fistula (FIE)
Date received	Dec 30, 2013
Decision date	Sep 11, 2014
Days to decision	255 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Nxstage Medical, Inc.**
Location	Tewksburt, MA, US
Contact	LAURA F PLATH
510(k) history	51 submissions · 51 cleared · 2001-2024