FDA 510(k) Premarket Notification

K180545 VACUETTE SAFELINK Holder with male luer lock

CLEARED

May 21, 2018
81 days to decision

K180545 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k180545/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Mar 1, 2018
Decision date	May 21, 2018
Days to decision	81 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Greiner Bio-One Na, Inc.**
Location	Monroe, NC, US
Contact	Manfred Abel
510(k) history	5 submissions · 5 cleared · 2016-2019