FDA 510(k) Premarket Notification

CLEARED

K211204 SafePort(TM) Manifold (or Stopcock)

Sep 15, 2022
511 days to decision

K211204 · Product code: **FMG** · General Hospital
Source: https://www.510kdatabase.net/k211204/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stopcock, I.v. Set (FMG)
Date received	Apr 22, 2021
Decision date	Sep 15, 2022
Days to decision	511 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Elcam Medical Acal**
Location	Phoenix, AZ, US
Contact	Avital Levertov
510(k) history	16 submissions · 16 cleared · 2003-2023