FDA 510(k) Premarket Notification

K200893 ProntoPump Sterile Tube Set

CLEARED

May 4, 2021
396 days to decision

K200893 · Product code: **LHI** · General Hospital
Source: https://www.510kdatabase.net/k200893/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, I.v. Fluid Transfer (LHI)
Date received	Apr 3, 2020
Decision date	May 4, 2021
Days to decision	396 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ipax, Inc.**
Location	CO, US
Contact	Jeff Baldwin
510(k) history	18 submissions · 18 cleared · 1984-2021