

**K200893 ProntoPump Sterile Tube Set**May 4, 2021  
396 days to decision

K200893 · Product code: LHI · General Hospital

Source: <https://www.510kdatabase.net/k200893/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200893/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 27, 2026