

**K221020 Accuryn Monitoring System, Accuryn SmartFoley IAP  
UO Temp Tray System 12 F, Accuryn SmartFoley IAP UO Temp  
Tray System 14 F**Jan 13, 2023  
282 days to decisionK221020 · Product code: **EZL** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k221020/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Apr 6, 2022
Decision date	Jan 13, 2023
Days to decision	282 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Potrero Medical, Inc.</b>
Location	San Francisco, CA, US
Contact	Priscila Tapia
510(k) history	2 submissions · 0 cleared · 2016-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221020/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 28, 2026