

**K192246 Biowy PICC Catheter S Kit**Apr 30, 2020  
255 days to decisionK192246 · Product code: **LJS** · General Hospital  
Source: <https://www.510kdatabase.net/k192246/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days (LJS)
Date received	Aug 19, 2019
Decision date	Apr 30, 2020
Days to decision	255 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Biowy Corporation</b>
Location	Lake Forest, CA, US
Contact	Arthur Lu
510(k) history	3 submissions · 3 cleared · 2018-2024

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192246/> 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