

K251980 ClaveQS™ BagMar 20, 2026
266 days to decisionK251980 · Product code: **KPE** · General Hospital
Source: <https://www.510kdatabase.net/k251980/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Container, I.v. (KPE)
Date received	Jun 27, 2025
Decision date	Mar 20, 2026
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Icu Medical, Inc.
Location	Walker, MI, US
Contact	Jeffrey Wan
510(k) history	66 submissions · 65 cleared · 1984-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251980/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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