

K240148 SCIg60 Infusion SystemFeb 16, 2024
28 days to decisionK240148 · Product code: **PKP** · General Hospital
Source: <https://www.510kdatabase.net/k240148/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Immunoglobulin G (igg) Infusion System (PKP)
Date received	Jan 19, 2024
Decision date	Feb 16, 2024
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Emed Technologies Corporation
Location	El Dorado Hills, CA, US
Contact	Olena Whalen
510(k) history	11 submissions · 11 cleared · 2012-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240148/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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