

K161906 SCIg60 InfuserDec 1, 2016
142 days to decisionK161906 · Product code: **PKP** · General Hospital
Source: <https://www.510kdatabase.net/k161906/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoglobulin G (igg) Infusion System (PKP)
Date received	Jul 12, 2016
Decision date	Dec 1, 2016
Days to decision	142 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161906/> Data sourced from FDA 510(k) public records (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. - Generated May 25, 2026