

K142319 SCIg60 Infuser, InfusetMay 14, 2015
267 days to decisionK142319 · Product code: **PKP** · General Hospital
Source: <https://www.510kdatabase.net/k142319/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Immunoglobulin G (igg) Infusion System (PKP) |
| Date received | Aug 20, 2014 |
| Decision date | May 14, 2015 |
| Days to decision | 267 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/k142319/> 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