

K251105 Tetra (TM-20)Dec 22, 2025
255 days to decisionK251105 · Product code: **PKP** · General Hospital
Source: <https://www.510kdatabase.net/k251105/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoglobulin G (igg) Infusion System (PKP)
Date received	Apr 11, 2025
Decision date	Dec 22, 2025
Days to decision	255 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Tetra (TM-50)

APPLICANT

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

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