

K181393 Empty Eva Bag, models FVM0134BP, FVM0135BP, FVM0136BP, FVM0137BP, FVM0138BP, FVM0139BP, FVM0140BP, FVM0141BPFeb 15, 2019
262 days to decisionK181393 · Product code: **KPE** · General Hospital
Source: <https://www.510kdatabase.net/k181393/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Container, I.v. (KPE)
Date received	May 29, 2018
Decision date	Feb 15, 2019
Days to decision	262 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Valmed S.R.L.
Location	Mazzo Di Valtellina So, IT
Contact	Parravicini Christian
510(k) history	2 submissions · 2 cleared · 2011-2019

REGULATORY CONSULTANT

Consulting firm	Studio Baggio Tiziana
Contact	Tiziana Baggio

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181393/> 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 June 19, 2026