

**K210749 Empty EVA Bag**Aug 19, 2021  
160 days to decisionK210749 · Product code: **KPE** · General HospitalSource: <https://www.510kdatabase.net/k210749/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Container, I.v. (KPE)
Date received	Mar 12, 2021
Decision date	Aug 19, 2021
Days to decision	160 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Haemotronic S.P.A.</b>
Location	Mirandola, IT
Contact	Franciosi Paola
510(k) history	2 submissions · 2 cleared · 2020-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210749/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026