

K193528 Empty EVA BagJul 22, 2020
216 days to decisionK193528 · Product code: **KPE** · General Hospital
Source: <https://www.510kdatabase.net/k193528/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Container, I.v. (KPE)
Date received	Dec 19, 2019
Decision date	Jul 22, 2020
Days to decision	216 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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