

K190328 HCT Empty EVA Container PackAug 15, 2019
183 days to decisionK190328 · Product code: **KPE** · General Hospital
Source: <https://www.510kdatabase.net/k190328/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Container, I.v. (KPE)
Date received	Feb 13, 2019
Decision date	Aug 15, 2019
Days to decision	183 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Health Care Technologies
Location	Ashland, MA, US
Contact	Adam T. Benson
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Mrc X, LLC
Contact	Dawn Norman

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190328/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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