

K143612 LifeCare PCA Infusion SystemApr 8, 2016
476 days to decisionK143612 · Product code: **MEA** · General Hospital
Source: <https://www.510kdatabase.net/k143612/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion, Pca (MEA)
Date received	Dec 19, 2014
Decision date	Apr 8, 2016
Days to decision	476 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hospira, Inc.
Location	Lake Forest, IL, US
Contact	Tom Gutierrez
Website	http://www.hospira.com
510(k) history	45 submissions · 44 cleared · 2004-2017

Hospira, Inc. was an American global pharmaceutical and medical device company headquartered in Lake Forest, Illinois. The company specialized in generic injectable pharmaceuticals and integrated infusion therapy systems for hospitals and alternate care settings. Hospira maintains an FDA 510(k) regulatory record of cleared devices from total submissions between 2004 and 2017. The company's primary focus was General Hospital devices, which comprised the majority of its submissions. Notable cleared products include the Plum 360 Infusion System, extension sets, administratio...
