

**K043256 HOSPIRA LIFECARE INFUSION SYSTEM, MODEL
12384-04-07**Dec 6, 2004
12 days to decisionK043256 · Product code: **MEA** · General Hospital
Source: <https://www.510kdatabase.net/k043256/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pump, Infusion, Pca (MEA)
Date received	Nov 24, 2004
Decision date	Dec 6, 2004
Days to decision	12 days
Third-party review	No
Summary / Statement	Summary
Other names	LIFECARE PCA INFUSION SYSTEM STERILE EMPY VIALS, MODEL 6021-04-03

APPLICANT

Company	Hospira, Inc.
Location	Lake Forest, IL, US
Contact	PATRICIA MELERSKI
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...