FDA 510(k) Premarket Notification

CLEARED

K161036 Hospira Extension Set, Hospira Primary Set

Jan 6, 2017
268 days to decision

K161036 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k161036/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Apr 13, 2016
Decision date	Jan 6, 2017
Days to decision	268 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hospira, Inc.**
Location	Lake Forest, IL, US
Contact	CHARLES NEITZEL
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...