FDA 510(k) Premarket Notification

CLEARED

K083019 GEMSTAR SP INFUSION SYSTEM WITH GEMSTAR SP INFUSION SUITE SOFTWARE

Oct 22, 2008
13 days to decision

K083019 · Product code: **FRN** · General Hospital
Source: https://www.510kdatabase.net/k083019/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	Oct 9, 2008
Decision date	Oct 22, 2008
Days to decision	13 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Hospira, Inc.**
Location	Lake Forest, IL, US
Contact	Yuliya Matlin
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...