FDA 510(k) Premarket Notification

K061450 HOSPIRA LATEX-FREE ADVANCED SENSOR CATHETERS

CLEARED

Aug 4, 2006
71 days to decision

K061450 · Product code: **DQE** · Cardiovascular
Source: https://www.510kdatabase.net/k061450/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Oximeter, Fiber-optic (DQE)
Date received	May 25, 2006
Decision date	Aug 4, 2006
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary
Other names	HOSPIRA LATEX-FREE CRITICAL CARE CATHETERS

APPLICANT

Company	**Hospira, Inc.**
Location	Lake Forest, IL, US
Contact	THOMAS SAMPOGNA
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...