FDA 510(k) Premarket Notification

CLEARED

K062999 OPTICATH CENTRAL VENOUS OXIMETRY PROBE WITH SEAL WITH HEPARIN

Nov 3, 2006
32 days to decision

K062999 · Product code: **DQE** · Cardiovascular
Source: https://www.510kdatabase.net/k062999/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Oximeter, Fiber-optic (DQE)
Date received	Oct 2, 2006
Decision date	Nov 3, 2006
Days to decision	32 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hospira, Inc.**
Location	Lake Forest, IL, US
Contact	DIANE RENNPFERD
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...