

**K061159 OPTICATH CENTRAL VENOUS OXIMETRY PROBE
WITH FLUIDIC SEAL WITH/WITHOUT HEPARIN**Jun 26, 2006
61 days to decisionK061159 · Product code: **DQE** · Cardiovascular
Source: <https://www.510kdatabase.net/k061159/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Oximeter, Fiber-optic (DQE)
Date received	Apr 26, 2006
Decision date	Jun 26, 2006
Days to decision	61 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

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