FDA 510(k) Premarket Notification

**CLEARED**

# K090610 HOSPIRA VITAL SIGNS WIRELESS MONITORING SYSTEM

Mar 13, 2009
7 days to decision

K090610 · Product code: **DRG** · Cardiovascular
Source: https://www.510kdatabase.net/k090610/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Transmitters And Receivers, Physiological Signal, Radiofrequency (DRG) |
| Date received | Mar 6, 2009 |
| Decision date | Mar 13, 2009 |
| Days to decision | 7 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...