MAUDE Adverse Event Report: PHILIPS MEDICAL SYSTEMS FETAL MONITOR SERIES 50 IP

PHILIPS MEDICAL SYSTEMS FETAL MONITOR SERIES 50 IP

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Model Number M1353A
Event Date 06/05/2010
Event Type Death
Event Description

The customer reported that a death occurred while a pt was being monitored by a philips fetal monitor.

Manufacturer Narrative

The customer reported that a death occurred while a pt was being monitored by a philips fetal monitor. The customer reported that the fetal monitor had given the baby's heart rate between 140 and 160bpm and then a range between 80bpm and 175bpm. Even when the baby was taken out of his mother, the monitor continued to show a rate of 140bpm whereas the baby was delivered stillborn. The available info is fully consistent with the clinicians monitoring the mother instead of the fetus. The available info is not sufficient to support that the use of the monitor was a factor in the stillbirth. Philips is in the process of obtaining additional info regarding this incident and the complaint is still under investigation. A final report will be submitted once the investigation is completed. (b) (4).

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Brand Name	FETAL MONITOR SERIES 50 IP
Manufacturer *(Section D)*	PHILIPS MEDICAL SYSTEMS Hewlett-Packard Str.2 Boeblingen 7103 4 GERMANY 71034
Manufacturer Contact	Nancy Sayer 3000 Minuteman Road Andover , MA 01810 9786597429
MDR Report Key	1729585
Report Number	9610816-2010-00195
Device Sequence Number	1
Product Code	HFM[24]

Report Source Manufacturer
Source Type Health Professional,User facility,Company Representative
Reporter Occupation Nurse
Type of Report Initial
Report Date 06/07/2010
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 06/16/2010
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? No
Device Operator Health Professional
Device MODEL Number M1353A
Was Device Available For Evaluation? Yes
Is The Reporter A Health Professional? Yes
Date Manufacturer Received 06/07/2010
Was Device Evaluated By Manufacturer? No
Date Device Manufactured 04/01/2003
Is The Device Single Use? No
Is this a Reprocessed and Reused Single-Use Device? No
Type of Device Usage Reuse

Patient TREATMENT DATA
Date Received: 06/16/2010 Patient Sequence Number: 1

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Page Last Updated: 01/31/2019

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