MAUDE Adverse Event Report: PHILIPS MEDICAL SYSTEMS FETAL MONITOR

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PHILIPS MEDICAL SYSTEMS FETAL MONITOR

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Model Number M1351A
Event Type Death
Manufacturer Narrative

The customer reported that when thy connected the mother to the monitor; they were receiving traces even though they were aware that the baby had previously died. The initial info is most consistent with monitoring the mother instead of the baby. Product labeling (instructions for use) adequately describes verification of fetal viability before monitoring and differentiation between the mother's heart rate (hr) and the baby's hr. Philips is in the process of obtaining add'l info regarding this incident, and the complaint is still under investigation. A final report will be submitted once the investigation is completed. (b) (4).

Event Description

The customer reported that when they connected the mother to the monitor, they were receiving traces even though they were aware that the baby had died at least 24 hours before the monitoring began.

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Brand Name	FETAL MONITOR
Manufacturer *(Section D)*	PHILIPS MEDICAL SYSTEMS Hewlett-Packard Str.2 Boeblingen 7103 4 GERMANY 71034
Manufacturer Contact	Nancy Sayer 3000 Minuteman Rd Andover , MA 01810 9786597429
MDR Report Key	1697304
Report Number	9610816-2010-00163
Device Sequence Number	1
Product Code	HFM[24]
Report Source	Manufacturer

Source Type Health Professional,User facility,Company Representative
Reporter Occupation Other
Type of Report Initial
Report Date 05/18/2010
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 05/20/2010
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? No
Device Operator Health Professional
Device MODEL Number M1351A
Was Device Available For Evaluation? Yes
Is The Reporter A Health Professional? Yes
Date Manufacturer Received 05/18/2010
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: 05/20/2010 Patient Sequence Number: 1

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Page Last Updated: 01/31/2019

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