MAUDE Adverse Event Report: PHILIPS MEDICAL SYSTEMS AVALON FM20 FETAL MONITOR

PHILIPS MEDICAL SYSTEMS AVALON FM20 FETAL MONITOR

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Model Number M2702A
Event Type Death
Event Description

The customer reported suspicious trace at the central monitoring/nurse station. The customer reported us signal had no typical doublebeat.

Manufacturer Narrative

The clinicians chose emergency c-section because of the suspicious trace. The baby was already deceased. Philips is in the process of obtaining additional information concerning this event and the complaint is still under investigation. A final report will be submitted once the investigation is completed.

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Brand Name	AVALON FM20 FETAL MONITOR
Manufacturer *(Section D)*	PHILIPS MEDICAL SYSTEMS Hewlett-Packard Str.2 Boeblingen 7103 4 GERMANY 71034
Manufacturer Contact	Greg Theokas 3000 Minuteman Rd Andover , MA 01810 9786871501
MDR Report Key	1409842
Report Number	9610816-2009-00070
Device Sequence Number	1
Product Code	HGM[24]
Report Source	Manufacturer
Source Type	Health Professional,User facility,Company Representative
Reporter Occupation	Other
Type of Report	Initial

Report Date 06/24/2009
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 06/30/2009
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? No
Device Operator Health Professional
Device MODEL Number M2702A
Was Device Available For Evaluation? Yes
Is The Reporter A Health Professional? Yes
Date Manufacturer Received 06/24/2009
Was Device Evaluated By Manufacturer? No
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: 06/30/2009 Patient Sequence Number: 1

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Page Last Updated: 01/31/2019

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