MAUDE Adverse Event Report: PHILIPS MEDICAL SYSTEMS AVALON FM30 FETAL MONITOR

PHILIPS MEDICAL SYSTEMS AVALON FM30 FETAL MONITOR

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Model Number M2703A
Event Type Death
Event Description

The customer alleged that the fm30 fetal monitor is not reliably monitoring and recording the fetal heart rate (fhr).

Manufacturer Narrative

(b)(4): the customer made an allegation that the avalon fm30 fetal monitor is not reliably monitoring and recording the fetal heart rate. The customer also reported that the avalon fm30 fetal monitor recorded a fetal heart rate despite the fact that the fetus was dead. The ccv feature was not being used. Maternal spo2 was not being measured. This complaint is being reported only because there was a fetal death and the monitor was in use. The available information does not indicate whether the fetal death occurred after the initiation of monitoring. Philips is in the process of obtaining additional information regarding this incident 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 FM30 FETAL MONITOR
Manufacturer *(Section D)*	PHILIPS MEDICAL SYSTEMS 3000 Minuteman Rd Andover MA 01810
Manufacturer Contact	Nancy Sayer 3000 Minuteman Road Andover , MA 01810 9786597429
MDR Report Key	1966936
Report Number	9610816-2011-00023
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 01/06/2011
1 **Device Was Involved in the Event**
1 **Patient Was Involved in the Event**
Date FDA Received 01/13/2011
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? No
Device Operator Health Professional
Device MODEL Number M2703A
Was Device Available For Evaluation? Yes
Is The Reporter A Health Professional? Yes
Date Manufacturer Received 01/06/2011
Was Device Evaluated By Manufacturer? No
Date Device Manufactured 09/01/2007
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: 01/13/2011 Patient Sequence Number: 1

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Page Last Updated: 01/31/2019

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