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 reported an incident where the ctg tracing for the fetal heart rate (fhr) was picking up the maternal heart rate (mhr) during labor and showing false positives. The hosp may have detected that the baby died in utero.

Manufacturer Narrative

The customer reported an incident where the ctg tracing for the fetal heart rate (fhr) was picking up the maternal heart rate (mhr) during labor after the hospital had detected that the baby died in utero. The clinicians verified that the fetus had no fhr by performing an ultrasound. The available info indicates that, during the verification of fetal viability that is normal clinical practice for fetal monitoring, the clinicians applied the internal fetal scalp electrode to the mother instead of the baby and derived the mhr instead of the fhr. In addition, the fetal monitoring by ultrasound also only could detect the mhr. The product labeling (instructions for use) warns clinicians to verify fetal life before beginning monitoring. There is no indication of any malfunction of the monitoring equipment or labeling (ifu). Philips is in the process of obtaining add'l info regarding this event 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	AVALON FM30 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	1618342
Report Number	9610816-2010-00041
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 02/01/2010
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 02/26/2010
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 02/01/2010
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: 02/26/2010 Patient Sequence Number: 1

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Page Last Updated: 01/31/2019

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