MAUDE Adverse Event Report: PHILLIPS MEDICAL PHILLIPS AVALON FETAL MONITOR

PHILLIPS MEDICAL PHILLIPS AVALON FETAL MONITOR

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Model Number AVALON FETAL
Event Date 05/30/2010
Event Type Death
Event Description

Still birth of a full term infant. Phillips medical fetal monitor indicated the infant had a heartbeat until the exact time of birth. At birth there was no heartbeat or respiratory effort. There was no response from infant despite a prolonged resuscitation process. There is now a question as to the accuracy of the fetal monitoring equipment. Was it recording the maternal heart rate after the infant unknowingly died in utero? this was an uncomplicated (b) (6) pregnancy. Autopsy was normal except for meconium present in the lungs as well as histiocytes that had ingested meconium. Also note that phillips had released an urgent medical device recall related to this equipment. (b) (4).

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Brand Name PHILLIPS AVALON FETAL MONITOR
Type of Device FETAL MONITOR
Manufacturer *(Section D)* PHILLIPS MEDICAL
3000 Minuteman Road
Andover MA 01810
MDR Report Key 1752476
Report Number MW5016627
Device Sequence Number 1
Product Code HGM[24]
Report Source Voluntary
Reporter Occupation Nurse
Type of Report Initial
Report Date 06/29/2010
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 06/29/2010
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? No

Device Operator Health Professional
Device MODEL NumberAVALON FETAL
Was Device Available For Evaluation?Yes
Is The Reporter A Health Professional?Yes
Is this a Reprocessed and Reused Single-Use Device?No

Patient TREATMENT DATA
Date Received: 06/29/2010 Patient Sequence Number: 1

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Page Last Updated: 01/31/2019

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