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
Manufacturer Narrative

(b)(4). The customer reported receiving a heart rate on a fetus that was deceased. Philips is in the process of obtaining additional info concerning this event and the complaint is still under investigation. A final report will be submitted once the investigation is completed.

Event Description

The customer reported receiving a heart rate on a fetus that was deceased.

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Brand Name AVALON FM20 FETAL MONITOR
Manufacturer *(Section D)* PHILIPS MEDICAL SYSTEMS
3000 Minuteman Rd
Andover MA 01810
Manufacturer Contact Denyse Murphy
3000 Minuteman Rd
Andover , MA 01810
9786597844
MDR Report Key 2168512
Report Number 9610816-2011-00387
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 07/06/2011
***1* Device Was Involved in the Event**

1 Patient Was Involved in the Event
Date FDA Received 07/08/2011
Is This An Adverse Event Report? No
Is This A Product Problem Report? Yes
Device Operator Health Professional
Device MODEL Number M2702A
Was Device Available For Evaluation? Yes
Is The Reporter A Health Professional? Yes
Date Manufacturer Received 07/06/2011
Was Device Evaluated By Manufacturer? No
Date Device Manufactured 11/01/2009
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: 07/08/2011 Patient Sequence Number: 1

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Page Last Updated: 01/31/2019

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