MAUDE Adverse Event Report: PHILIPS MEDICAL SYSTEMS AVALON FM50 FETAL MONITOR

PHILIPS MEDICAL SYSTEMS AVALON FM50 FETAL MONITOR

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Model Number M2705A
Event Date 08/02/2013
Event Type Death
Manufacturer Narrative
(b)(4). A follow up report will be submitted after philips obtains more information concerning this event.

Event Description
The customer reported that the avalon fm50 fetal monitor was wrongly tracing a heart rate, and recorded a heart rate last night on a baby that had been born deceased.

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Brand Name	AVALON FM50 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	3504303
Report Number	9610816-2013-00180
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	08/02/2013

1 Device Was Involved in the Event
1 Patient Was Involved in the Event
Date FDA Received 08/08/2013
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? No
Device Operator Health Professional
Device MODEL Number M2705A
Was Device Available For Evaluation? Yes
Is The Reporter A Health Professional? Yes
Date Manufacturer Received 08/02/2013
Was Device Evaluated By Manufacturer? No
Date Device Manufactured 02/01/2013
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: 08/08/2013 Patient Sequence Number: 1

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Page Last Updated: 01/31/2019

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