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 07/31/2013
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 a fetal death while monitoring with an avalon fm50 fetal monitor. The customer requested that an audible inop for the coincidence detection alerts be introduced.

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Brand Name	AVALON FM50 FETAL MONITOR
Manufacturer *(Section D)*	PHILIPS MEDICAL SYSTEMS 3000 Minuteman Rd Andover MA 01810
Manufacturer Contact	Greg Theokas 3000 Minuteman Rd Andover , MA 01810 9786871501
MDR Report Key	3299684
Report Number	9610816-2013-00173
Device Sequence Number	1
Product Code	HGM[24]
Report Source	Manufacturer
Source Type	Foreign,User facility
Reporter Occupation	Other
Type of Report	Initial
Report Date	07/31/2013

1 Device Was Involved in the Event
0 PatientS WERE Involved in the Event:
Date FDA Received 08/14/2013
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
Date Manufacturer Received 07/31/2013
Was Device Evaluated By Manufacturer? No
Date Device Manufactured 08/01/2012
Is The Device Single Use? No
Is this a Reprocessed and Reused Single-Use Device? No
Type of Device Usage Reuse

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