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 01/07/2010
Event Type Death
Event Description

On february 12, 2010, philips received a medwatch report stating that the baby died one day after the delivery.

Manufacturer Narrative

On february 12, 2010, philips received a medwatch stating that the baby died one day after the delivery. The customer made it clear in the medwatch that there have been difficulties distinguishing between the baby's and the maternal hr. And therefore, a c-section was performed. The customer made it clear that the clinicians were aware of the issue and made no allegation or indication that the device contributed to the death. In addition, there is no allegation of a product malfunction. Philips is in the process of obtaining additional 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 FM50 FETAL MONITOR
Manufacturer *(Section D)*	PHILIPS MEDICAL SYSTEMS Hewlett-Packard Str.2 Boeblingen 7103 4 GERMANY 71034
Manufacturer Contact	Nancy Sayer 3000 Minuteman Road Andover , MA 01810 9786597429
MDR Report Key	1622600
Report Number	9610816-2010-00042
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 01/07/2010
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 03/01/2010
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 02/12/2010
Was Device Evaluated By Manufacturer? No
Date Device Manufactured 05/01/2009
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: 03/01/2010 Patient Sequence Number: 1

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