MAUDE Adverse Event Report: PHILIPS MEDICAL SYSTEMS AVALON FM30 FETAL MONITOR

PHILIPS MEDICAL SYSTEMS AVALON FM30 FETAL MONITOR

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Model Number M2703A
Event Type Death
Manufacturer Narrative

The customer made an allegation of a unappropriated c-section and fetal death. Philips has not verified that there was a fetal death or what was the condition of the fetus when monitoring began. Philips is in the process of obtaining additional info regarding this incident and the complaint is still under investigation. A final report will be submitted once the investigation is completed.

Event Description

The customer made an allegation of a unappropriated c-section and fetal death.

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Brand Name	AVALON FM30 FETAL MONITOR
Manufacturer *(Section D)*	PHILIPS MEDICAL SYSTEMS 3000 Minuteman Rd Andover MA 01810
Manufacturer Contact	Nancy Sayer 3000 Minuteman Rd Andover , MA 01810 9786597429
MDR Report Key	1957267
Report Number	9610816-2010-00865
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	12/23/2010

1 Device Was Involved in the Event
1 Patient Was Involved in the Event
Date FDA Received 01/05/2011
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? No
Device Operator Health Professional
Device MODEL Number M2703A
Was Device Available For Evaluation? Yes
Is The Reporter A Health Professional? Yes
Date Manufacturer Received 12/23/2010
Was Device Evaluated By Manufacturer? No
Is this a Reprocessed and Reused Single-Use Device? No
Type of Device Usage Reuse

Patient TREATMENT DATA
Date Received: 01/05/2011 Patient Sequence Number: 1

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Page Last Updated: 01/31/2019

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