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 Date 06/01/2011
Event Type Death
Event Description

The customer reported that while monitoring with a philips avalon fm30 fetal monitor, a fetus was stillborn.

Manufacturer Narrative

(b)(4). The customer reported that while monitoring with a philips avalon fm30 fetal monitor, a fetus was stillborn. According to the doctor, the system functionality is not according to specification as there were heart sounds although the fetus was stillborn. The available information gives no indication that these users verified fetal life before initiating monitoring (as specified in device labeling). 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.

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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 Ataide 3000 Minuteman Road Andover , MA 01810 9786597429
MDR Report Key	2129896
Report Number	9610816-2011-00324
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 06/01/2011
1 **Device Was Involved in the Event**
1 **Patient Was Involved in the Event**
Date FDA Received 06/08/2011
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 06/01/2011
Was Device Evaluated By Manufacturer? No
Date Device Manufactured 02/01/2007
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: 06/08/2011 Patient Sequence Number: 1

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Page Last Updated: 01/31/2019

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