MAUDE Adverse Event Report: PHILIPS MEDICAL SYSTEMS AVALON FM20 FETAL MONITOR

PHILIPS MEDICAL SYSTEMS AVALON FM20 FETAL MONITOR

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Model Number M2702A
Event Date 10/19/2009
Event Type Death
Manufacturer Narrative

The customer did not measure the mother's heart rate with a continuous measurement (spo2 or mecg), so the cross channel verification (ccv) algorithm could not generate warnings. The labeling (ifu) is clear that the user should confirm the fetal live with an independent means before using the fetal monitor. The device was tested afterwards and no malfunction was found. Philips has not determined if failing to use any ccv or verification of fetal life prevented some therapy that might have changed the outcome. 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.

Event Description

The customer reported that the ctg was giving a fetal rate reading of 160 bpm, but yet, the baby was stillborn after an emergency c-section was performed.

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Brand Name AVALON FM20 FETAL MONITOR
Manufacturer *(Section D)* PHILIPS MEDICAL SYSTEMS
Hewlett-Packard Str. 2
Boeblingen 7103 4
GERMANY 71034
Manufacturer Contact Nancy Sayer
3000 Minuteman Rd.
Andover , MA 01810
9786597429
MDR Report Key 1545370
Report Number 9610816-2009-00206
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	10/19/2009
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	11/12/2009
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device MODEL Number	M2702A
Was Device Available For Evaluation?	Yes
Is The Reporter A Health Professional?	Yes
Date Manufacturer Received	10/19/2009
Was Device Evaluated By Manufacturer?	No
Date Device Manufactured	02/01/2009
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: 11/12/2009 Patient Sequence Number: 1

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Page Last Updated: 01/31/2019

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