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 08/07/2009
Event Type Death
Event Description

The customer reported that a pregnant pt was admitted and although had a normal fetal hr, a caesarian section found the baby had macerated at least 48 hours prior to the surgery.

Manufacturer Narrative

This adverse event is being considered as reportable since it is a death where an allegation has been made that the device was a factor in the death. It is confirmed that the baby was dead for more than 48 hours. It is not confirmed for how long the monitoring was ongoing before it was decided to do the c-section (--more or less than 48 hours?). Therefore, we cannot confirm from the available info that the use of this device was not a factor in the death. This event was reported to the philips on 10/28/2009. We have not been able to determine if any philips representatives were aware of this event before 10/28/2009. The customer did not measure the mother's heart rate with a continuous measurement (spo2 and mecg) so the cross channel verification (ccv) algorithm could not generate warnings if the clinicians were monitoring the mother instead of the baby. The labeling is clear that the user should confirm the fetal life with an independent means before using the fetal monitor. Doing this would have detected that the baby might have been already dead. We will consider that the use outside that described in the labeling--neither confirming life before monitoring nor using the ccv functionality--delayed the clinician knowing that the baby was dead. The available info does not allow us to determine if knowing the status of the baby could have impacted the outcome. Philips is in the process of investigating this event and a final report will be submitted once the investigation has been completed.

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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 1545883
Report Number 9610816-2009-00205
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 08/12/2009
***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 08/12/2009
Was Device Evaluated By Manufacturer? No
Date Device Manufactured 04/01/2008
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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