MAUDE Adverse Event Report: PHILIPS MEDICAL SYSTEMS SERIES 50 XM FETAL/MATERNAL MONITOR

[6]

PHILIPS MEDICAL SYSTEMS SERIES 50 XM FETAL/MATERNAL MONITOR

Back to Search Results

Model Number M1350C
Event Type Death
Event Description

The customer reported that the device was a factor in the death of an infant during childbirth.

Manufacturer Narrative

The customer reported that the device was a factor in the death of an infant during childbirth. 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. The customer used a fetal scalp electrode to monitor the fetal ecg and heartrate, but the fetal monitor showed the maternal hr. The midwife did not regard the fetal scalp ecg or the difference between the fetal scalp electrode and the ultrasound ecg. The midwife did not notice that the fetus died. There is no indication that there was any comparison of the ultrasound fhr to the mother's heart rate as specified in the fetal monitoring instructions for use (ifu). Philips is in the process of obtaining add'l info regarding this event and the complaint is still under investigation. A final report will be submitted once the investigation is completed.

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Brand Name	SERIES 50 XM FETAL/MATERNAL 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	1545367
Report Number	9610816-2009-00207
Device Sequence Number	1
Product Code	HGM[24]
Report Source	Manufacturer

Source Type Health Professional,User facility,Company Representative
Reporter Occupation
Type of Report Initial
Report Date 11/09/2009
1 **Device Was Involved in the Event**
1 **Patient Was Involved in the Event**
Date FDA Received 11/13/2009
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? No
Device Operator HEALTH PROFESSIONAL
Device MODEL Number M1350C
Was Device Available For Evaluation? Yes
Is The Reporter A Health Professional? Yes
Date Manufacturer Received 11/09/2009
Was Device Evaluated By Manufacturer? No
Date Device Manufactured 06/01/2001
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: 11/13/2009 Patient Sequence Number: 1

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20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
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Page Last Updated: 03/31/2019

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