MAUDE Adverse Event Report: PHILIPS HEALTHCARE, INC. PHILIPS AVALON FM50 FETAL MONITOR

PHILIPS HEALTHCARE, INC. PHILIPS AVALON FM50 FETAL MONITOR

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Model Number FM 20
Device Problems False Device Output; False Reading From Device Non-Compliance
Event Date 11/30/2009
Event Type Death
Event Description

A pt presenting to labor and delivery in labor. At 41 week gestation and history of prior planned c-section for twins. Patient placed on fm20 philips avalon. Monitor was erratic with tracings and at one point, it was difficult to distinguish mom and baby's heart rate on the tracing, but the digital readout was 30 beats apart. Ultrasound showed no heart beat. Emergency c-section was performed and the infant had an apgar of 0,0. The infant was resuscitated and transferred to facility with higher level of care in nicu. The baby did not survive, dying the next day.

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Brand Name PHILIPS AVALON FM50
Type of Device FETAL MONITOR
Manufacturer *(Section D)* PHILIPS HEALTHCARE, INC.
3000 Minuteman Road
Andover MA
MDR Report Key 1579412
Report Number 1579412
Device Sequence Number 1
Product Code HGM[24]
Report Source User Facility
Source Type Unknown
Reporter Occupation RISK MANAGER
Type of Report Initial
Report Date 01/08/2010
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 01/08/2010
Is This An Adverse Event Report? Yes

Is This A Product Problem Report? No
Device Operator Health Professional
Device MODEL Number FM 20
Device Catalogue Number M2702A
Device LOT Number 865701
OTHER Device ID Number 59-43089
Was Device Available For Evaluation? Yes
Is The Reporter A Health Professional? Yes
Was the Report Sent to FDA? Yes
Date Report Sent to FDA 01/08/2010
Distributor Facility Aware Date 12/31/2009
Device Age 4 mo
Event Location Hospital
Date Report TO Manufacturer 01/07/2010
Was Device Evaluated By Manufacturer? No Answer Provided
Is this a Reprocessed and Reused Single-Use Device? No
Type of Device Usage Invalid Data

Patient TREATMENT DATA
Date Received: 01/08/2010 Patient Sequence Number: 1
Treatment
HAND-HELD DOPPLER
INTERNAL FETAL MONITOR

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Page Last Updated: 01/31/2019

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