MAUDE Adverse Event Report: PHILIPS MEDICAL SYSTEMS AVALON FM50 FETAL MONITOR

PHILIPS MEDICAL SYSTEMS AVALON FM50 FETAL MONITOR

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Model Number M2705A
Event Date 10/14/2014
Event Type Death
Manufacturer Narrative
(b)(4). A follow up report will be submitted after philips obtains more information concerning this event.

Event Description
The customer reported that a female who has had one pregnancy and no live births presented in active labor ((b)(6)) to labor and delivery with contractions. During the second stage of labor, an emergent c-section was required due to fetal bradycardia that was not apparent on the electronic fetal monitor until an internal fetal scalp electrode was placed. At the time the bradycardia was discovered, the c-section was performed. The baby had a triple nuchal cord, born with no detectible heart rate and neonatal resuscitation program was initiated. The pt was transported to the nicu in critical condition. The infant was resuscitated post-partum, and transferred to (b)(6) where they determined the infant had no brain activity thus transferred back. This was a post-term infant with (b)(6) complete weeks of gestation. The baby was delivered asystolic, and required full resuscitation including intubation, positive pressure ventilation (ppv), chest compression, multiple epinephrine doses and central line placement. Her apgars where 0, 0, and 0 at 1, 5 and 10 minutes. Heart rate was obtained approximately 13 minutes into resuscitation. Severe hypoxic ischemic encephalopathy; the family with drew life support and infant expired two days later.

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Brand Name AVALON FM50 FETAL MONITOR
Manufacturer *(Section D)* PHILIPS MEDICAL SYSTEMS
Hewlett-Packard Str. 2
Boeblingen 7103 4
GERMANY 71034
Manufacturer Contact Denyse Murphy
3000 Minuteman Road
Andover , MA 01810
9786597844
MDR Report Key 4351506
Report Number 9610816-2014-00316

Device Sequence Number 1
Product Code HGM[24]
Report Source Manufacturer
Source Type User facility
Reporter Occupation Other
Type of Report Initial
Report Date 11/18/2014
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 12/15/2014
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? No
Device Operator Health Professional
Device MODEL Number M2705A
Was Device Available For Evaluation? Yes
Date Manufacturer Received 11/18/2014
Was Device Evaluated By Manufacturer? No
Date Device Manufactured 11/01/2009
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: 12/15/2014 Patient Sequence Number: 1

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Page Last Updated: 01/31/2019

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