MAUDE Adverse Event Report: HUNTLEIGH HEALTHCARE LTD. DIAGNOSTICS SONICAID FM800 RANGE OF FETAL MONITOR

[6]

HUNTLEIGH HEALTHCARE LTD. DIAGNOSTICS SONICAID FM800 RANGE OF FETAL MONITOR

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Model Number FM830
Device Problem Insufficient Information
Event Date 12/28/2011
Event Type Death
Manufacturer Narrative

This report is being filed under exemption (b)(4) on behalf of the manufacturer huntleigh healthcare ltd. (registration#1000589001). The unit is being returned from (b)(6) hospital to the service department at (b)(6) for investigation. Additional information will be provided following the conclusion of the manufacturer's investigation.

Event Description

A communication was received from the adverse incident centre of the (b)(6), stating that an incident had been reported by (b)(6) hospital with regard to an fm830 fetal monitor. The reported fault with the monitor was "ctg displaying trace with fetal heart rate of 150bpm, but baby was dead. ".

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Brand Name	SONICAID
Type of Device	FM800 RANGE OF FETAL MONITOR
Manufacturer *(Section D)*	HUNTLEIGH HEALTHCARE LTD. DIAGNOSTICS Cardiff UNITED KINGDOM
Manufacturer *(Section G)*	HUNTLEIGH HEALTHCARE LTD. DIAGNOSTICS 35 Portmanmoor Rd Cardiff, South Glamorgan CF2 2HB UNITED KINGDOM CF2 2HB
Manufacturer Contact	Steve Hellstrom 2349 West Lake St. Addison , IL 60101 8003231245
MDR Report Key	2444284

Report Number 1000589001-2012-00001
Device Sequence Number 1
Product Code HGM[24]
Report Source Manufacturer
Source Type Other,Foreign
Reporter Occupation NOT APPLICABLE
Type of Report Initial
Report Date 02/03/2012,01/06/2012
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 02/08/2012
Is This An Adverse Event Report? No
Is This A Product Problem Report? Yes
Device Operator Health Professional
Device MODEL Number FM830
Was Device Available For Evaluation? Yes
Date Returned to Manufacturer 11/08/2010
Is The Reporter A Health Professional? No
Was the Report Sent to FDA? Yes
Date Report Sent to FDA 02/03/2012
Distributor Facility Aware Date 01/10/2012
Event Location Hospital
Date Report TO Manufacturer 02/03/2012
Date Manufacturer Received 01/06/2012
Was Device Evaluated By Manufacturer? Device Not Returned To Manufacturer
Is The Device Single Use? No
Is this a Reprocessed and Reused Single-Use Device? No
Type of Device Usage Unkown

Patient TREATMENT DATA
Date Received: 02/08/2012 Patient Sequence Number: 1

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Page Last Updated: 01/31/2019

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