MAUDE Adverse Event Report: HUNTLEIGH HEALTHCARE LTD, DIAGNOSTICS SONICAID

HUNTLEIGH HEALTHCARE LTD, DIAGNOSTICS SONICAID

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Model Number FM830ENCORE
Device Problem Adverse Event Without Identified Device or Use Problem
Event Date 05/12/2014
Event Type Death
Event Description

A (b)(6) gestation fetus who was delivered stillborn (at the end of the trace at 21:27). The baby was very oedematous and swollen and difficult to deliver: there were antenatal complications which were not previously known. The preliminary post mortem report suggests that the fetus had died at least 12 hours prior to delivery i. E. Before the monitoring started. The trace seems to reflect the presence of a fetal heart rate but it does not appear to be the same as the maternal heart rate. Reference mfr report number: 1000589001-2014-00002.

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Brand Name	SONICAID
Manufacturer *(Section D)*	HUNTLEIGH HEALTHCARE LTD, DIAGNOSTICS 35 Portmanmoor Rd Cardiff
Manufacturer *(Section G)*	ARJO, INC. 50 North Gary Ave., Suite A Roselle IL 60172 168
Manufacturer Contact	50 North Gary Ave., Suite A Roselle , IL 60172-1684
MDR Report Key	3935231
Report Number	1419652-2014-00168
Device Sequence Number	1
Product Code	HGM[24]
Report Source	Distributor
Source Type	Unknown
Reporter Occupation	RISK MANAGER
Type of Report	Initial
Report Date	06/26/2014,06/19/2014

1 Device Was Involved in the Event
1 Patient Was Involved in the Event
Date FDA Received06/27/2014
Is This An Adverse Event Report?Yes
Is This A Product Problem Report?No
Device OperatorHEALTH PROFESSIONAL
Device MODEL NumberFM830ENCORE
Was Device Available For Evaluation?No
Is The Reporter A Health Professional?Yes
Was the Report Sent to FDA?Yes
Date Report Sent to FDA06/26/2014
Distributor Facility Aware Date06/19/2014
Event Location Hospital
Date Report TO Manufacturer06/26/2014
Is this a Reprocessed and Reused Single-Use Device?No

Patient TREATMENT DATA
Date Received: 06/27/2014 Patient Sequence Number: 1

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Page Last Updated: 03/31/2019

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