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

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HUNTLEIGH HEALTHCARE LTD. DIAGNOSTICS SONICAID FM800 RANGE OF FETAL MONITORS

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Model Number FM830ENCORE

Event Type Death

Event Description

Clinicians have had difficulty distinguishing between the fhr and mhr. The customer did an operation and a fetus was still born yet the fhr was showing ok.

Manufacturer Narrative

(b)(4) is submitting the report on behalf huntleigh (b)(4). ((b)(4)) for more details.

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Brand NameSONICAID
Type of DeviceFM800 RANGE OF FETAL MONITORS
Manufacturer (Section D)HUNTLEIGH HEALTHCARE LTD. DIAGNOSTICS
35 Portmanmoor Rd.
Cardiff
Manufacturer (Section G)HUNTLEIGH HEALTHCARE LTD. DIAGNOSTICS
35 Portmanmoor Rd.
Cardiff
Manufacturer ContactSteve Kahn
2349 West Lake St.
Addison , IL 60101
8003231245
MDR Report Key3030183
Report Number1000589001-2013-00002
Device Sequence Number1
Product Code[HGM](#)²⁴
Report SourceManufacturer
Source TypeForeign

Reporter OccupationOther**Type of Report**Initial**Report Date**03/27/2013,02/27/2013**1 Device Was Involved in the Event****1 Patient Was Involved in the Event****Date FDA Received**03/28/2013**Is This An Adverse Event Report?**Yes**Is This A Product Problem Report?**No**Device Operator**Health Professional**Device MODEL Number**FM830ENCORE**Was Device Available For Evaluation?**No**Is The Reporter A Health Professional?**No**Was the Report Sent to FDA?**Yes**Date Report Sent to FDA**03/27/2013**Distributor Facility Aware Date**02/27/2013**Device Age**1 yr**Event Location**Hospital**Date Report TO Manufacturer**03/27/2013**Date Manufacturer Received**02/27/2013**Was Device Evaluated By Manufacturer?**Device Not Returned To Manufacturer**Date Device Manufactured**04/01/2012**Is The Device Single Use?**No**Is this a Reprocessed and Reused Single-Use Device?**No**Type of Device Usage**Invalid Data**Patient TREATMENT DATA****Date Received: 03/28/2013 Patient Sequence Number: 1****Links on this page:**

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Page Last Updated: 01/31/2019

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U.S. Department of **Health & Human Services**

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