FDA MAUDE Database Search for Deltex Medical Competitor Incidents

A search of the FDA Manufacturer and User Facility Device Experience (MAUDE) Database was conducted to find reported incidents related to Deltex Medical competitor devices. The CardioQ Cardiac Output and Fluid Status Monitoring System received FDA 510(k) approval in August 2003 and deemed substantially equivalent to the Arrow International Hemosonic 100 Cardiac Output Monitor (originally approved as the Sometec, Inc. DYNEMO 3000) – 510(K) No. K972798. As a result the following search criteria was used and the results can be found attached:

1) Date Report Received by FDA: "01/01/1980" to "05/27/2010"
2) Brand Name: "HEMOSONIC"
3) Manufacturer: "ARROW"
4) Manufacturer: "SOMETEC"
5) Brand Name: "DYNEMO"
6) 510K Number: "K972798"

The search resulted in one incident being identified for the Arrow Hemosonic 100 Monitoring System (see attached).

In addition a search was conducted for another competitors device; the TECO monitor manufactured by Medicina Limited and the following search criteria was used:

1) Date Report Received by FDA: "01/01/1980" to "05/27/2010"
2) Brand Name: "TECO"
3) Manufacturer: "MEDICINA"

The search resulted in no records being found.

Signed on behalf of Deltex Medical Limited by:

Lawrence Brookfield
Regulatory Affairs Manager
Date: 25/05/10
MAUDE - Manufacturer and User Facility Device Experience

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Search MAUDE Database

<table>
<thead>
<tr>
<th>Product</th>
<th>Problem</th>
<th>Product</th>
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</thead>
<tbody>
<tr>
<td>Class</td>
<td>Brand Name</td>
<td>HEMOSONIC</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>510K Number</td>
<td>K</td>
</tr>
<tr>
<td>Event Type</td>
<td>PMA Number</td>
<td>P</td>
</tr>
<tr>
<td></td>
<td>Product Code</td>
<td></td>
</tr>
</tbody>
</table>

Date Report Received by FDA (mm/dd/yyyy)

01/01/1980 to 05/27/2010

Enter one or a combination of the MAUDE Search Values and select Search

For full-text search, select Go To Simple Search button

Go to Simple Search

10 Records per Report Page

Medical Device Reporting Search: (for incidents before July 31, 1996)
MAUDE Adverse Event Report

ARROW INTERNATIONAL, INC. ARROW HEMOSONIC 100 SYSTEM
HEMOSONIC MONITORING SYSTEM

Catalog Number HSM-00100
Device Problem Unknown (for use when the device problem is not known)
Event Type Injury Patient Outcome Required Intervention;
Event Description
It was reported that the device was in use to monitor a pt with an abdominal aortic aneurysm using only total cardiac output from the monitor. The physician did not consider the other factors such as systemic vascular resistance, changes in blood flow, stroke volume, etc. Based on only the cardiac output readings, he gave the pt fluids. As a result of the user error, the pt developed pulmonary edema. The pt recovered and there were no complications.

Manufacturer Narrative
Evaluations: based on the reported info, this situation appears to be the result of user error. There is no indication of any product malfunction or defect. Apparently, the user did not consider all necessary factors prior to making decisions that affect the pt's condition. This is an unusual, use related report that has been addressed by addtional education. Management will continue to monitor reports of this type. No other action indicated. The sample will not be returned.

Search Alerts/Recalls

New Search | Submit an Adverse Event Report

Brand Name ARROW HEMOSONIC 100 SYSTEM
Type of Device HEMOSONIC MONITORING SYSTEM
Baseline Brand Name ARROW HEMOSONIC 100 SYSTEM
Baseline Generic Name HEMOSONIC MONITORING SYSTEM
Baseline Catalogue Number HSM-00100
Manufacturer (Section D)
2400 Bernville Rd
Reading , PA 19605
2400 Bernville Rd
Reading , PA 19605
(610) 478 -3159
Device Event Key 278119
MDR Report Key 287417
Event Key 269664
Report Number 1219856-2000-00184
Device Sequence Number 1
Product Code DPW
Report Source Manufacturer
Source Type Health Professional
Reporter Occupation UNKNOWN
Type of Report Initial, Followup
Report Date 07/25/2000

1 Device Was Involved in the Event
1 Patient Was Involved in the Event

Date FDA Received 07/28/2000

Is This An Adverse Event Report? Yes
Is This A Product Problem Report? No

Device Operator Health Professional
Device Catalogue Number HSM-00100

Was Device Available For Evaluation? No

Is The Reporter A Health Professional? Yes

Was the Report Sent to FDA? No
Date Manufacturer Received 07/14/2000

Was Device Evaluated By Manufacturer? No

Is The Device Single Use? No
Is the Device an Implant? No
Is this an Explanted Device? No

Type of Device Usage Unknown

Patient TREATMENT DATA
Date Received: 07/28/2000 Patient Sequence Number: 1

<table>
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<tr>
<th>#</th>
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</table>
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Search MAUDE Database

Product
Problem
Product
Class
Brand Name
Manufacturer ARROW
510K Number K
PMA Number P
Event Type
Product Code
Date Report Received by FDA (mm/dd/yyyy) 01/01/2000 to 05/27/2010

Enter one or a combination of the MAUDE Search Values and select Search. For full-text search, select Go To Simple Search button

Go to Simple Search 10 Records per Report Page Search Clear

Medical Device Reporting Search: (for incidents before July 31, 1996)
<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Brand Name</th>
<th>Date Report Received</th>
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<tbody>
<tr>
<td>ARROW INTL., INC.</td>
<td>AUTOCAT2 WAVE</td>
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<td>CVC SET: 2-LUMEN 7FR</td>
<td>03/19/2010</td>
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<tr>
<td>ARROW INTL., INC.</td>
<td>SINGLE TRAY KIT</td>
<td>03/19/2010</td>
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<td>ARROW INTL., INC.</td>
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<td>ARROW INTL., INC.</td>
<td>CATH PKGD: BERMAN 4</td>
<td>03/19/2010</td>
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<td>ARROW INTERNATIONAL</td>
<td>ARROWGARD BLUE PLUS</td>
<td>03/19/2010</td>
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<td>ARROW INTL., INC.</td>
<td>PERC. THROMBOLYTIC D</td>
<td>03/16/2010</td>
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None relate to predicate devices. Jul 27/05/10
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<td>Event Type</td>
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510K Number K
PMA Number P
Product Code

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Go to Simple Search 10 Records per Report Page Search Clear

Medical Device Reporting Search: (for incidents before July 31, 1996)
MAUDE - Manufacturer and User Facility Device Experience

No records were found with
Manufacturer: SOMELEC
Report Date From: 01/01/1980
Report Date To: 05/27/2010
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<tr>
<td>Brand Name</td>
<td>DYNEMO</td>
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Go to Simple Search 10 Records per Report Page Search Clear

Medical Device Reporting Search; (for incidents before July 31, 1996)
New Search
No records were found with
Brand Name: DYNEMO Report Date From: 01/01/1980 Report Date To: 05/27/2010
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Product
Problem
Product
Class
Brand Name
Manufacturer
Event Type

510K Number K972798
PMA Number
Product Code

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Medical Device Reporting Search: (for incidents before July 31, 1996)
### MAUDE - Manufacturer and User Facility Device Experience

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<th>Registration &amp; Listing</th>
<th>Adverse Events</th>
<th>Recalls</th>
<th>PMA</th>
<th>Classification</th>
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<td>Radiation-Emitting Products</td>
<td>X-Ray Assembler</td>
<td>Medsun Reports</td>
<td>CLIA</td>
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</tr>
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New Search

No records were found with

**510(K) Number:** K972798  **Report Date From:** 01/01/1980  **Report Date To:** 05/27/2010
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Product
Problem
Product
Class

Brand Name 510K Number K
Manufacturer MEDICINA PMA Number P
Event Type Product Code

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MAUDE - Manufacturer and User Facility Device Experience

New Search

No records were found with
Manufacturer: MEDICINA Report Date From: 01/01/1980 Report Date To: 05/27/2010
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Product
Problem
Product
Class
Brand Name TEO
Manufacturer
Event Type

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Go to Simple Search
10 Records per Report Page

Medical Device Reporting Search: (for incidents before July 31, 1996)
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<th>Brand Name</th>
<th>Date Report Received</th>
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<tbody>
<tr>
<td>DFINE INC.</td>
<td>VERTECOR MIDLINE CEM</td>
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<td>ARTHREX, INC.</td>
<td>SCREW.BIO-TECODESIS,</td>
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<td>MEDCOMP</td>
<td>11.5FX20CM TECOTHANE</td>
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None relate to predicate devices for 03/05/10.

Report Date From: 01/01/1980  Report Date To: 05/27/2010

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