

IUPC's & Patient Risk

FDA adverse event reports associated with two IUPC's.

Results taken from FDA's MAUDE online database.

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM>

To search for reports associated with the **INTRAN® Plus** or **Koala®** IUPC, navigate web browser to the MAUDE online database and fill in the fields as highlighted below:

Search MAUDE Database Help | Download Files | More About MAUDE

Product Problem

Product Class

Brand Name 510K Number

Manufacturer PMA Number

Event Type Product Code

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

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

Records per Report Page

What is the MAUDE database?

The Manufacturer And User Device Experience or MAUDE database represents reports of adverse events involving medical devices. The online search allows you to search CDRH (Center for Devices and Radiological Health) database information on medical devices which may have malfunctioned or caused a death or serious injury.

(Source: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM>)

UTAH MEDICAL
PRODUCTS INC.



One Avoidable Bad Outcome is Too Many.

Search results for INTRAN® Plus:

10 records meeting your search criteria returned - Brand Name: *Intran* Report Date From: 01/01/2000 Report Date To: 07/31/2011

New Search		Help Download Files More about MAUDE	
Manufacturer	Brand Name		Date Report Received
UTAH MEDICAL PRODUCT	INTRAN PLUS IUP-400	No Patient Injury	03/20/2009
UTAH MEDICAL PRODUCT	INTRAN PLUS IUP-400	No Patient Injury	02/25/2009
UTAH MEDICAL PRODUCT	INTRAN PLUS IUP-400	No Patient Injury	02/11/2009
UTAH MEDICAL PRODUCT	INTRAN PLUS IUP-400	No Patient Injury	12/18/2008
UTAH MEDICAL PRODUCT	INTRANPLUS IUP-C50	No Patient Injury	10/09/2008
EVERA MEDICAL, INC.	EVERA INTRANASAL SPL	Not an IUPC	10/04/2007
EVERA MEDICAL, INC.	EVERA INTRANASAL SPL	Not an IUPC	08/17/2007
UTAH MEDICAL PRODUCT	INTRAN PLUS	No Patient Injury	07/08/2005
UTAH MEDICAL	INTRAN PLUS	No Patient Injury	11/15/2004
UTAH MEDICAL PROD IN	INTRAN PLUS IUP-400	No Patient Injury	03/01/2001

*INTRAN® Plus has been used in approximately 2 million deliveries since Jan. 2000 and has been associated with NO reported patient injuries. INTRAN® Plus has never been subject to a product liability lawsuit.

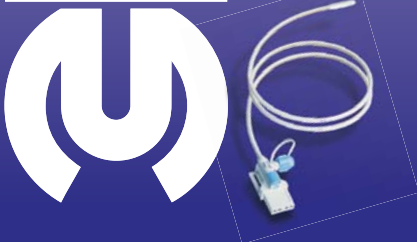
Search results for Koala®:

13 records meeting your search criteria returned - Brand Name: *Koala* Report Date From: 01/01/2000 Report Date To: 08/31/2011

New Search		Help Download Files More about MAUDE	
Manufacturer	Brand Name		Date Report Received
CLINICAL INNOVATIONS	KOALA IPC 5000	Serious Injury	08/18/2011
CLINICAL INNOVATIONS	CATHETER IUPC EXTERN	Death	05/27/2011
CLINICAL INNOVATIONS	KOALA	Serious Injury	01/13/2011
CLINICAL INNOVATIONS	KOALA	Death	01/29/2010
CLINICAL INNOVATIONS	KOALA	Death	01/28/2008
CLINICAL INNOVATIONS	KOALA IPC 5000	Serious Injury	10/30/2007
CLINICAL INNOVATION	KOALA IPC 5000	Serious Injury	09/04/2007
CLINICAL INNOVATION	KOALA IPC 5000	Serious Injury	09/04/2007
CLINICAL INNOVATIONS	KOALA INTRAUTERINE P	Death	06/08/2006
PERMOBIL AB	CHAIRMAN KOALA	Not an IUPC	11/26/2003
CLINICAL INNOVATIONS	KOALA	Serious Injury	09/22/2003
CLINICAL INNOVATIONS	KOALA	Serious Injury	08/16/2003
CLINICAL INNOVATIONS	KOALA	Serious Injury	02/07/2003

Note: A detailed description of each adverse event report may be found by clicking on the underlined link in the "Brand Name" column.

UTAH MEDICAL
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INTRAN[®] PLUS IUPC.



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