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MAUDE Adverse Event Report



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WALLY NATURAL PRODUCTS WALLY JOES' EAR CANDLES

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Event Date 12/10/2007

Event Type Injury

Event Description

My boyfriend wanted to try ear candling. I think that these should be banned or at least a very hazardous warning put on packaging. The packaging was all cute. It ended up that the hot wax went down his ear and burnt a hole through his ear drum. The fda needs to get more involved with the selling -or rather non-distribution- of ear candles. These are very dangerous to say the least. Dates of use: one time use and stopped. In 2007. Diagnosis or reason for use: to clear out ear wax.

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Brand Name WALLY NATURAL PRODUCTS

Type of Device WALLY JOES' EAR CANDLES

Device Event Key 940287

MDR Report Key 970302

Event Key 931113

Report Number MW5004776

Device Sequence Number 1

Product Code JYH

Report Source Voluntary

Reporter Occupation Patient FAMILY MEMBER OR FRIEND

Type of Report Initial

Report Date 12/20/2007

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received 12/20/2007

Is This An Adverse Event Report? Yes

Is This A Product Problem Report? No

Device Operator Service Personnel

Was Device Available For Evaluation? Device Returned To Manufacturer

Date Returned to Manufacturer 12/20/2007

Is The Reporter A Health Professional? No

Was The Report Sent To Manufacturer? No

Is this a Reprocessed and Reused Single-Use Device? No

Is the Device an Implant? No

Is this an Explanted Device?

Patient TREATMENT DATA

Date Received: 12/20/2007 Patient Sequence Number: 1

#	Treatment	Treatment Date
1,	WALLY'S NATURAL EAR CANDLES	