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MAUDE Adverse Event Report

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WALLY'S WALLY'S EAR CANDLE Back to Search Results

Event Date 08/21/2006

Event Type Other **Patient Outcome** Other;

Event Description

Patient used an ear candle. States she felt a burning sensation in her right ear. Our initial exam demonstrated what appeared to be "wax". On follow -up 1 week later, the tympanic membrane was examined and a perforation was identified.

Search Alerts/Recalls

New Search | Submit an Adverse Event Report

Brand Name	WALLY'S
Type of Device	EAR CANDLE
Manufacturer *(Section D)*	WALLY'S *
Device Event Key	748606
MDR Report Key	760688
Event Key	725208
Report Number	MW1040425
Device Sequence Number	1
Product Code	JYH
Report Source	Voluntary
Reporter Occupation	Physician
Type of Report	Initial

Report Date	09/06/2006
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	09/06/2006
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Lay User/Patient
Was Device Available For Evaluation?	No
Is The Reporter A Health Professional?	Yes
Was the Report Sent to FDA?	No
Event Location	Home
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?	No Answer Provided