U.S. Food & Drug Administration

MAUDE Adverse Event Report:

Event Type Injury **Patient Outcome** Life Threatening
Event Description
This product was advertized to cure sinusitis and clean earwax. Product is mislabeled and fda needs to investigate. This product is a fraud. Patient was burnt from using this product.

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MDR Report Key1013928
Event Key972796
Report NumberMW5005889
Report Source Voluntary
Reporter Occupation Patient
Type of Report Initial,Followup
Report Date08/10/2007
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received08/10/2007
Is This An Adverse Event Report?No
Is This A Product Problem Report?Yes
Is The Reporter A Health Professional?No
Was the Report Sent to FDA?No
Was The Report Sent To Manufacturer?No
Is this a Reprocessed and Reused Single-Use Device?No

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.fda.gov/MedicalDevices/default.htm
5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. ../cfPMN/pmn.cfm
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9. ../cfMAUDE/TextSearch.cfm
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20. http://www.fda.gov/MedicalDevices/Safety/default.htm
21. https://www.accessdata.fda.gov/scripts/medwatch/

Page Last Updated: 10/31/2012

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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- Website Policies

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Email FDA

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20. http://www.fda.gov/MedicalDevices/Safety/default.htm
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