

Summary

WAVE has detected the following:

- 0 Errors
- 3 Alerts
- 2 Features
- 5 Structural Elements
- 4 HTML5 and ARIA
- 8 Contrast Errors

Panel Options

- DETAILS: A listing of all the WAVE icons in your page.
- DOCUMENTATION: Explanation of the WAVE icons and how you can make your page more accessible.
- OUTLINE: The heading structure of the web page.

DISPLAYING TRENDS IN
MEDICAL DEVICE SAFETY

Displaying Trends In Medical Device Safety



Medical Devices

Adverse Events

Enforcement Reports

About

Home X2

ADVERSE EVENTS & ENFORCEMENT REPORTS
FOR MEDICAL DEVICES

h1 Value Statement:

In support of FDA's mission to protect the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. This site provides information related to trends in medical device safety and information about adverse events and enforcement reports reported by medical device manufacturers.

h1 Data Constraints

This data is retrieved directly from FDA using APIs in support of a prototype development demonstration. The intent of the prototype is to support data visualization techniques to help inform users and decision-makers interested in medical device safety

h4 Contact Us/Feedback:



Logo*

*Ace Info Solutions, Inc



h2 Ace Info Solutions, Inc.

GSA ADS I BPA-FDA Prototype Team

11490 Commerce Park Dr. Suite #340

Reston VA 20191

Phone: 703-391-2800

Fax: 703-391-2833

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Summary

WAVE has detected the following:

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ADVERSE EVENTS & ENFORCEMENT REPORTS FOR MEDICAL DEVICES

Adverse Events Report by Year and Manufacturer



Year: 2000



Manufacturer: Abbott Laboratories




Device Types (Top 25)



Severity of Adverse Events

Loading...

Loading...



WAVE

web accessibility evaluation tool

<http://medicaldevicesafety-aceinfo.el:→>

Styles

No Styles

Contrast

Summary

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0 Errors

2 Alerts


1 Features

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58 Contrast Errors


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DISPLAYING TRENDS IN MEDICAL DEVICE SAFETY

alt

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ADVERSE EVENTS & ENFORCEMENT REPORTS FOR MEDICAL DEVICES








h1

Highest Number of Enforcement Reports by Manufacturer for the Current Year (2015)

thManufacturers	thTotal
Navilyst Medical, Inc	60
Nobel Biocare Usa Llc	26
Wright Medical Technology, Inc.	23
Intuitive Surgical, Inc.	23
Teleflex Medical	20
GE Healthcare	17
Stryker Instruments Div. of Stryker Corporation	16
Siemens Medical Solutions USA, Inc	16
Trumpf Medical Systems, Inc.	12
Siemens Medical Solutions USA, Inc.	11
Microtek Medical Inc	11
Synthes, Inc.	10
Specialty Appliance Works, Inc.	10
Roche Diagnostics Operations, Inc.	10
Churchill Medical Systems, Inc.	10

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7/6/2015



http://medicaldevicesafety-aceinfo.el:→

Styles No Styles Contrast

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Medical Devices Adverse Events Enforcement Reports About



ADVERSE EVENTS & ENFORCEMENT REPORTS FOR MEDICAL DEVICES

h1 Latest Adverse Events

th Date	th Manufacturer	th Device	th Event
04.27.2015	Depuy Orthopaedics, Inc.	Hip Acetabular Inser...	Injury
04.20.2015	Av Temecula Ct	Suture Mediated Clos...	Injury
04.16.2015	Ge Oec Medical Systems	Fluoroscopic X Ray	Injury
04.06.2015	3006356043 Johnson & Johnson M...	Shoulder Head/Glenos...	Injury
04.02.2015	Boston Scientific Neuromodulat...	Spinal Cord Stimulat...	Injury

View More

h1 Latest Enforcement Reports

th Date	th Manufacturer	th Status	th Classification
04.29.2015	Richard Allan Scientific Compa...	Ongoing	Class II
04.29.2015	Richard Allan Scientific Compa...	Ongoing	Class II
04.28.2015	Covidien Llc	Ongoing	Class II
04.23.2015	Philips Medical Systems, Inc.	Ongoing	Class II
04.17.2015	Mitsubishi Heavy Industries, L...	Ongoing	Class II

View More

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h1 Adverse Events and Enforcement Reports by Device Type and Year



Device Type: AC Powered Hospital Bed

