

fdalerts

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1 Registration

FDA

Food and Drug Safety Alert System

Registration

First Name

Enter first name.

Middle Name

Enter middle name.

Last Name

Enter last name.

Email

Email address.

Phone

Phone number.

Zipcode

Zipcode.

Register

A

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Validate all fields for proper input; Prompt user if input is invalid. [A]

Prevent pressing of Register button if input is invalid. [B]

Widget Specifications

| | |
|----------------------------|--|
| Registration | Page |
| >Box / Section rounded | Section |
| >>Heading 3 "Registration" | Text |
| >>Primary - large | Button |
| On click | Pick an event 4 [Login] Go To Page:Login Case Sensitive:no |
| >>Table 2 | Table |

| | |
|---------------------------------------|-----------|
| >>>TableRow | TableRow |
| >>>>TableCell | TableCell |
| >>>>>Column Head <i>"First Name"</i> | Text |
| >>>>TableCell | TableCell |
| >>>>>Text Input | TextInput |
| >>>TableRow | TableRow |
| >>>>TableCell | TableCell |
| >>>>>Row Content <i>"Middle Name"</i> | Text |
| >>>>TableCell | TableCell |
| >>>>>Text Input | TextInput |
| >>>TableRow | TableRow |
| >>>>TableCell | TableCell |
| >>>>>Last Name <i>"Last Name"</i> | Text |
| >>>>TableCell | TableCell |
| >>>>>Text Input | TextInput |
| >>>TableRow | TableRow |
| >>>>TableCell | TableCell |
| >>>>>Email <i>"Email"</i> | Text |
| >>>>TableCell | TableCell |
| >>>>>Text Input | TextInput |
| >>>TableRow | TableRow |
| >>>>TableCell | TableCell |
| >>>>>Phone <i>"Phone"</i> | Text |
| >>>>TableCell | TableCell |
| >>>>>Text Input | TextInput |
| >>>TableRow | TableRow |
| >>>>TableCell | TableCell |
| >>>>>Zipcode <i>"Zipcode"</i> | Text |
| >>>>TableCell | TableCell |

| | |
|----------------|------------|
| >>>>Text Input | TextInput |
| >Header | Master Ref |
| >Footer | Master Ref |

2 Login

FDA

Food and Drug Safety Alert System

Login

Email address

Password

Sign In

Register an account

Register at FDAlerts for alerts on:

Adverse events

FDA's publicly available drug adverse event and medication error reports, and medical device adverse event reports

Recalls

Enforcement report data, containing information gathered from public notices about certain recalls of FDA-regulated products

Labeling

Structured Product Labeling (SPL) data for FDA-regulated human prescription drug, OTC drug and biological product labeling

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Widget Specifications

| | |
|--|-----------|
| Login | Page |
| >Box / Section rounded | Section |
| >>Text Input | TextInput |
| >>Text Input | TextInput |
| >>Heading 3 "Login" | Text |
| >>Primary - large | Button |
| On click Pick an event 3 [Preferences] Go To Page:Preferences Case Sensitive:no | |
| >>Register an "Register an account" | Text |
| On click Pick an event 1 [Action Sequence 1] Go To Page:Registration Case Sensitive:no | |

| | |
|--|------------|
| >Box / Section filled | Section |
| >Register at "Register at FDAAlerts for alerts on:" | Text |
| >Adverse events: "Adverse events: " | Text |
| >Recalls: "Recalls: " | Text |
| >Labeling: "Labeling: " | Text |
| >FDA's publically "FDA's publically available drug adverse event and " | Text |
| >Enforcement report "Enforcement report data, containing information ga" | Text |
| >Structured Prodcut "Structured Product Labeling (SPL) data for FDA-reg" | Text |
| >Header | Master Ref |
| >Footer | Master Ref |
| >Box / Section | Section |

3 Preferences

FDA

Food and Drug Safety Alert System

Set your preferences

Preference

Drug

Preference

Device

Preference

Food

Add Preferences

Search

Search for Drug

A

Search

Search for Device

B

Search

Search for Food

C

Add Keyword

Add Keyword

Add Keyword

Save

Click on 'View Report' for reports

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Support type-ahead lookup [A][B][C]

Widget Specifications

| | |
|------------------------------------|-----------------|
| Preferences | Page |
| >Box / Section rounded | Section |
| >>Heading 3 "Set your preferences" | Text |
| >>Primary - large | Button |
| >>Label "Preference" | Text |
| >>Select | Select-Standard |
| >>Label "Search" | Text |
| >>TextInput 1 | TextInput |
| >>Label "Preference" | Text |

| | |
|---|-----------------|
| >>Select | Select-Standard |
| >>Label "Search" | Text |
| >>TextInput 1 | TextInput |
| >>Label "Preference" | Text |
| >>Select | Select-Standard |
| >>Label "Search" | Text |
| >>TextInput 1 | TextInput |
| >>Add Preferences | Button |
| >>Section 1 | Section |
| >>Heading 3 "Click on 'View Report' for reports" | Text |
| >>Save | Button |
| >>Save | Button |
| >>Save | Button |
| >Header | Master Ref |
| >Footer | Master Ref |

4 Saved Preferences

FDA

Food and Drug Safety Alert System

Set your preferences

PreferenceDrugAdvilView Report

PreferenceDevicePacemakerView Report

PreferenceFoodPeanutsView Report

Add Preferences

Adverse Events

| Manufacture Name | Generic Name | Model Number | Event Type | Date of Event |
|------------------|--|--------------|-------------|---------------|
| MPRI | DRUG ELUTING PERMANENT RIGHT VENTRICULAR (RV) OR RIGHT ATRIAL (RA) PACEMAKER ELE | 5086MR145 | Malfunction | 12-31-1969 |

Enforcement Reports

| Recalling Firm | Product Description | Reason for Recall | Recall Init Date |
|--|--|--|------------------|
| Medtronic Inc. Cardiac Rhythm Disease Management | Medtronic Temporary Pacemaker, Model 5348. Single Chamber External Pulse Generator (EPG) Temporary Pacemaker (AAI/VI). Used in conjunction with a cardiac pacing lead system for temporary atrial or ventricular pacing in a clinical environment. The device is typically | Events related to a pacing rate outside of the intended setting, including events of sudden increased pacing rate up to the maximum setting of 18- pulses per minutes (ppm), have been reported. | 12-31-1969 |

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Support type-ahead lookup

Widget Specifications

| | |
|------------------------------------|---------|
| Saved Preferences | Page |
| >Box / Section rounded | Section |
| >>Heading 3 "Set your preferences" | Text |
| >>Primary - large | Button |
| >>Label "Preference" | Text |
| >>Label "Preference" | Text |
| >>Label "Preference" | Text |
| >>Section 1 | Section |
| >>Add Keyword | Button |

>>Add Keyword Button

On click Pick an event 6
[Switch Views] Switch Views
Case Sensitive:no

>>Add Keyword Button

>>Drug "Drug" Text

>>Advil "Advil" Text

>>Device "Device" Text

>>Pacemaker "Pacemaker" Text

>>Food "Food" Text

>>Peanuts "Peanuts" Text

>>Reports DD Dynamic Display

>>>Click for Reports Section

>>>>Heading 3 "Click on 'View Report' for reports" Text

>>>>View Report for Pacemaker Section

>>>>Heading 3 "Adverse Events" Text

>>>>Heading 3 "Enforcement Reports" Text

>>>>Table 1 Table

>>>>>TableRow TableRow

>>>>>>TableCell TableCell

>>>>>>Manufacture Name "Manufacture Name" Text

>>>>>>TableCell TableCell

>>>>>>Generic Name "Generic Name" Text

>>>>>>TableCell TableCell

>>>>>>Model Number "Model Number" Text

>>>>>>TableCell TableCell

>>>>>>Event Type "Event Type" Text

>>>>>>TableCell TableCell

>>>>>>Date of "Date of Event" Text

>>>>>TableRow TableRow

>>>>>>TableCell TableCell

| | | |
|---------------------------|---|------------|
| >>>>>>MPRI | MPRI | Text |
| >>>>>>TableCell | | TableCell |
| >>>>>>DRUG ELUTING | DRUG ELUTING PERMANENTRIGHT VENTRICULAR (RV) ORR | Text |
| >>>>>>TableCell | | TableCell |
| >>>>>>5086MR145 | 5086MR145 | Text |
| >>>>>>TableCell | | TableCell |
| >>>>>>Malfunction | Malfunction | Text |
| >>>>>>TableCell | | TableCell |
| >>>>>>12-31-1969 | 12-31-1969 | Text |
| >>>>>>Table 2 | | Table |
| >>>>>>TableRow | | TableRow |
| >>>>>>TableCell | | TableCell |
| >>>>>>Recalling Firm | Recalling Firm | Text |
| >>>>>>TableCell | | TableCell |
| >>>>>>Product Description | Product Description | Text |
| >>>>>>TableCell | | TableCell |
| >>>>>>Reason for | Reason for Recall | Text |
| >>>>>>TableCell | | TableCell |
| >>>>>>Recall Init | Recall Init Date | Text |
| >>>>>>TableRow | | TableRow |
| >>>>>>TableCell | | TableCell |
| >>>>>>Medtronic Inc. | Medtronic Inc. Cardiac RhythmDisease Management | Text |
| >>>>>>TableCell | | TableCell |
| >>>>>>Medtronic Temporary | Medtronic Temporary Pacemaker, Model 5348.Single | Text |
| >>>>>>TableCell | | TableCell |
| >>>>>>Events related | Events related to a pacing rateoutside of the int | Text |
| >>>>>>TableCell | | TableCell |
| >>>>>>12-31-1969 | 12-31-1969 | Text |
| >Header | | Master Ref |

5 Header

FDA Food and Drug Safety Alert System

Widget Specifications

| | |
|---|---------|
| Header | Master |
| >Box / Section | Section |
| >FDA "FDA" | Text |
| >Food and "Food and Drug Safety Alert System" | Text |

6 Footer

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Widget Specifications

| Footer | | Master |
|----------------|---|---------|
| >Box / Section | | Section |
| >Powered by | "Powered by Rigil Corporation" | Text |
| >Visit Rigil | | Button |
| On click | Pick an event 5 [http://www.rigil.com] Go To http://www.rigil.com (open in pop-up x:100;y:100;height:0;width:0) Case Sensitive:no | |

