Company Name:	**ABCDEFE MEDICAL, INC.**
Website:	
Country:	
Report Date Range:	**January 1, 2010 – April 30, 2018**

KEY METRICS

Record Type

Check All | Uncheck All

- [x] Adverse Event Report (9,165)
- [x] Recall (2)

Report Type

Check All | Uncheck All

- [x] Malfunction (7,839)
- [x] *blank* (1,269)
- [x] Death (55)
- [x] Injury (1)
- [x] Other (1)

Report Source

Check All | Uncheck All

- [x] Manufacturer report (9,164)
- [x] Voluntary report (1)

Reporter Occupation

Check All | Uncheck All

- [x] NOT APPLICABLE (4,674)
- [x] PATIENT (3,920)
- [x] OTHER (523)
- [x] *blank* (46)
- [x] AUDIOLOGIST (1)
- [x] PHYSICIAN (1)

Product Code

Check All | Uncheck All

- [x] MKJ (9,167) Automated External Defibrillator (Non-Wearable)

Device Class

Check All | Uncheck All

- [x] 3 (9,165)

Medical Specialty

Check All | Uncheck All

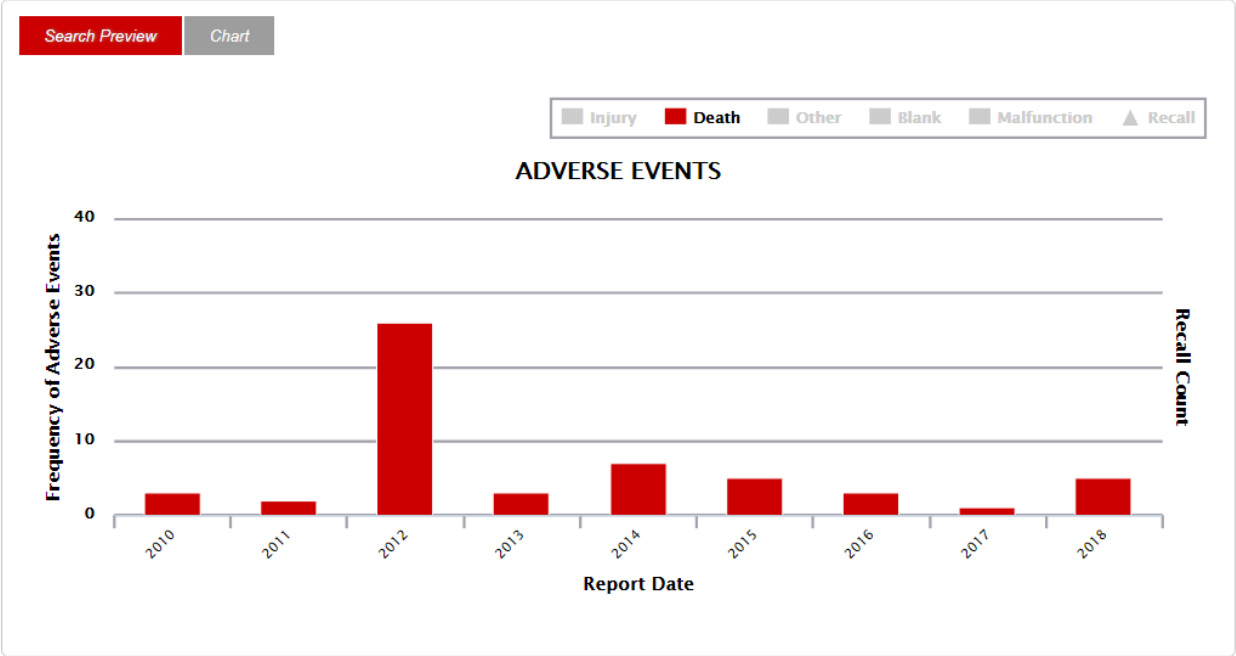
- [x] CV (9,165) Cardiovascular

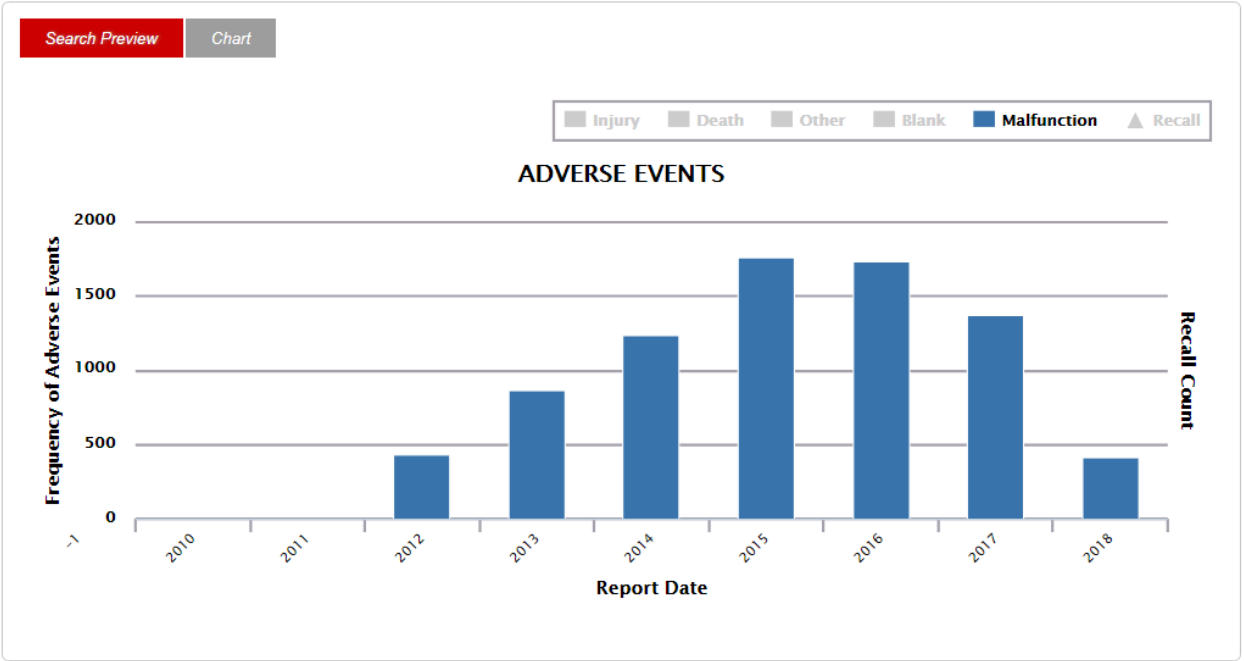
Period

Check All | Uncheck All

- [x] 2010 (5)
- [x] 2011 (4)
- [x] 2012 (461)
- [x] 2013 (2,141)
- [x] 2014 (1,246)
- [x] 2015 (1,772)
- [x] 2016 (1,739)
- [x] 2017 (1,377)
- [x] 2018 (422)

TRENDS


Search Preview
Chart
Injury
Death
Other
Blank
Malfunction
Recall
ADVERSE EVENTS
Frequency of Adverse Events
Recall Count
40
30
20
10
0
2010
2011
2012
2013
2014
2015
2016
2017
2018
Report Date


Search Preview
Chart
Injury
Death
Other
Blank
Malfunction
Recall
ADVERSE EVENTS
Frequency of Adverse Events
Recall Count
2000
1500
1000
500
0
-1
2010
2011
2012
2013
2014
2015
2016
2017
2018
Report Date

EXAMPLE REPORT

EXAMPLE DEATH REPORT

Manufacturer report: Death

[redacted]

reporter occupation: 000 OTHER
MAUDE link: xxxxxxxxxxxxxxxxxxxxxxxxxxxx

dates

Report Date: 2018-03-07
Event Date: 2018-02-10
Mfr Rec'd Date: 2018-02-12
FDA Rec'd Date: 2018-03-07
Date Added: 2018-03-07
Date Changed: 2018-03-07

device

- **product code:** MKJ
- **device name:** Automated External Defibrillators (Non-Wearable)
- **brand:** [redacted]
- **generic:** AUTOMATED EXTERNAL DEFIBRILLATOR
- **operator:** 0LP LAY USER/PATIENT
- **model #:**
- **catalog #:** [redacted]
- **lot #:**
- **other ID #:**
- **evaluated by manufacturer:** N
- **available:** Y
- **expires:**
- **PMA/510K #:**

description

PATIENT INVOLVED. DEVICE DID NOT TURN ON. PATIENT DID NOT SURVIVE.

other elements

- mdr-report-key: [redacted]
- report-number: [redacted]
- manufacturer-link-flag-: Y
- adverse-event-flag: Y
- product-problem-flag: N
- date-report: 2018-03-07
- date-of-event: 2018-02-10
- reprocessed-and-reused-flag: N
- health-professional: I
- date-manufacturer-received: 2018-02-12
- single-use-flag: N
- previous-use-code: I
- date-added: 2018-03-07
- date-changed: 2018-03-07
- event-type: D
- event-type-description: Death

- report-source-code: M
- report-source-description: Manufacturer report
- reporter-occupation-code: 000
- reporter-occupation-description: OTHER
- initial-report-to-fda: *
- initial-report-to-fda-description: No answer provided
- report-to-fda: *
- report-to-fda-description: No answer provided
- type-of-report: I
- type-of-report-description: Initial submission
- source-type: DISTRIBUTOR
- source-type-description: DISTRIBUTOR
- remedial-action: IN
- remedial-action-description: Inspection
- event-location: I
- name: [redacted]
- original-name: [redacted]
- street-1: [redacted]
- city: [redacted]
- zip-code: [redacted]
- zip-code-ext: [redacted]
- postal-code: [redacted]
- text: EXEMPTION NUMBER CONCOMITANT MEDICAL PRODUCTS. [redacted] (MANUFACTURER) IS SUBMITTING THE REPORT ON (B)(4). NOT RETURNED YET.
- text: PATIENT INVOLVED. DEVICE DID NOT TURN ON. PATIENT DID NOT SURVIVE.
- device-sequence-no: 1.0
- date-received: 2018-03-07
- brand-name: [redacted]
- generic-name: AUTOMATED EXTERNAL DEFIBRILLATOR
- catalog-number: [redacted]
- device-availability: Y
- device-evaluated-by-manufactur: N
- device-operator: 0LP
- device-operator-description: LAY USER/PATIENT
- device-report-product-code: MKJ
- device-name: Automated External Defibrillators (Non-Wearable)
- medical-specialty-code: CV
- medical-specialty-description: Cardiovascular
- review-panel-code: CV
- review-panel-description: Cardiovascular
- device-class-code: 3
- device-class-description: Devices subject to General Controls, Special Controls, and Premarket Clearance
- third-party-review-eligible-code: N
- third-party-review-eligible-description: Not Eligible for Accredited Persons Program
- submission-type-code: 2
- submission-type-description: PMA
- patient-sequence-number: 1
- date-received: 2018-03-07
- sequence-number-outcome: 1. D

----------end of report----------

EXAMPLE MALFUNCTION REPORTS

Manufacturer report : Malfunction

[redacted]

reporter occupation: 305 PATIENT
MAUDE
link: [redacted]

dates

Report Date: 2017-10-18
Event Date: 2017-08-25
Mfr Rec'd Date: 2017-08-25
FDA Rec'd Date: 2017-09-21
Date Added: 2017-09-21
Date Changed: 2017-10-20

device

- **product code:** MKJ
- **device name:** Automated External Defibrillators (Non-Wearable)
- **brand:** [redacted]
- **generic:** AUTOMATED EXTERNAL DEFIBRILLATOR
- **operator:** 0LP LAY USER/PATIENT
- **model #:** [redacted]
- **catalog #:** [redacted]
- **lot #:**
- **other ID #:**
- **evaluated by manufacturer:** Y
- **available:** R
- **expires:**
- **PMA/510K #:**

description

NO PATIENT INVOLVED. DEVICE OBSERVED SWITCHING ON AUTOMATICALLY.

other elements

- mdr-report-key: [redacted]
- report-number: [redacted]
- manufacturer-link-flag-: Y
- adverse-event-flag: N
- product-problem-flag: Y
- date-report: 2017-10-18
- date-of-event: 2017-08-25
- reprocessed-and-reused-flag: N
- health-professional: N
- date-facility-aware: 2017-08-25
- report-date: 2017-09-18
- date-report-to-manufacturer: 2017-09-18
- date-manufacturer-received: 2017-08-25
- device-date-of-manufacture: 2009-08-03
- single-use-flag: N
- previous-use-code: U
- removal-correction-number: [redacted]

- date-added: 2017-09-21
- date-changed: 2017-10-20
- event-type: M
- event-type-description: Malfunction
- report-source-code: M
- report-source-description: Manufacturer report
- reporter-occupation-code: 305
- reporter-occupation-description: PATIENT
- initial-report-to-fda: N
- initial-report-to-fda-description: No
- report-to-fda: N
- report-to-fda-description: No
- event-location: I
- name: [redacted]
- original-name: [redacted]
- street-1: [redacted]
- street-2: [redacted]
- city: [redacted]
- state-code: [redacted]
- zip-code: [redacted]
- country-code: [redacted]
- postal-code: [redacted]
- text: (B)(4).
- text: NO PATIENT INVOLVED. DEVICE OBSERVED SWITCHING ON AUTOMATICALLY.
- device-sequence-no: 1.0
- date-received: 2017-09-21
- brand-name: [redacted]
- generic-name: AUTOMATED EXTERNAL DEFIBRILLATOR
- model-number: [redacted]
- catalog-number: [redacted]
- device-availability: R
- date-returned-to-manufacturer: 2017-09-22
- device-age-text: 8 YR
- device-evaluated-by-manufactur: Y
- device-operator: 0LP
- device-operator-description: LAY USER/PATIENT
- device-report-product-code: MKJ
- device-name: Automated External Defibrillators (Non-Wearable)
- medical-specialty-code: CV
- medical-specialty-description: Cardiovascular
- review-panel-code: CV
- review-panel-description: Cardiovascular
- device-class-code: 3
- device-class-description: Devices subject to General Controls, Special Controls, and Premarket Clearance
- third-party-review-eligible-code: N
- third-party-review-eligible-description: Not Eligible for Accredited Persons Program
- submission-type-code: 2
- submission-type-description: PMA
- patient-sequence-number: 1
- date-received: 2017-09-21

----------end of report----------

*** END OF DOCUMENT ***