OPENFDA MEDICAL DEVICE ADVERSE EVENT ANALYSIS

Analysis of FDA Medical Device Adverse Event Reports

BVI Medical

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1. Executive Summary

This report analyzes **127** FDA medical device adverse event reports submitted between **November 10, 2016** and **October 16, 2025** (a period of **107.2** months). The dataset includes **1** unique manufacturers and **28** unique device brands. The average reporting rate was **2.3** reports per month, with peak reporting of **19** reports in **September 2025**.

Table 1: Summary statistics of FDA MAUDE reports

Metric	Value
Total Reports	127
Date Range	November 10, 2016 to October 16, 2025
Reporting Duration	3262 days (107.2 months)
Unique Manufacturers	1
Unique Device Brands	28
Average Monthly Reports	2.3 reports/month
Maximum Monthly Reports	19 reports in September 2025

2. Methodology

2.1. Data Source

The search of the FDA Manufacturer and User Facility Device Experience (MAUDE) database was conducted using the openFDA Device Event API. Retrieved JSON-formatted data were downloaded directly from the API and subsequently processed and cleaned for analysis.

2.2. Data Standardization and Fuzzy Matching

The analysis uses automated text matching to standardize manufacturer and brand names across reports. FDA MAUDE reports often contain variations in spelling, capitalization, and formatting (e.g., "INC", "Inc.", or "LLC").

Names with ≥75% similarity are grouped together under a single standardized name. This reduces data fragmentation and provides more accurate counts.

> **i** Note
>
> For technical details on the fuzzy matching algorithm, see Section 8.3.1 in the Technical Appendix.

2.3. Problem Classification and Data Quality Filters

Patient and product problems are extracted and categorized, excluding non-informative categories to focus on meaningful data patterns.

Key Considerations:

- Individual reports may list multiple product problems per incident
- Individual reports may list multiple patient problems per incident
- Total problem occurrences can exceed the total number of reports
- Each problem occurrence is counted separately to identify the most frequent failure modes and issues

> **i** Note
>
> For the complete list of excluded categories, see Section 8.4 in the Technical Appendix.

2.4. Concentration-Based Analysis Methodology

This analysis identifies the critical few problems, manufacturers, and brands that account for the majority of occurrences. Rather than selecting an arbitrary "top 10", we dynamically identify categories that collectively represent approximately 80% of all reported occurrences.

Categories are ranked by frequency, and those accounting for approximately 80% of the data are analyzed in detail. The remaining items are grouped as "Other(s)". This approach ensures no category is artificially split.

> **i** Note
>
> For implementation details, see Section 8.3.2 in the Technical Appendix.

2.5. Statistical Analysis of Temporal Trends

Monthly reporting patterns are analyzed using standard statistical methods to identify unusual increases or decreases in reporting activity.

Variability Metrics: Standard deviation and coefficient of variation measure how much monthly reports fluctuate around the average.

Peak and Valley Detection: Months with unusually high or low reporting (more than 2 standard deviations from average) are flagged as statistically significant.

> **i** Note
>
> For detailed statistical methodology, see Section 8.3.3 in the Technical Appendix.

3. Temporal Trend Analysis
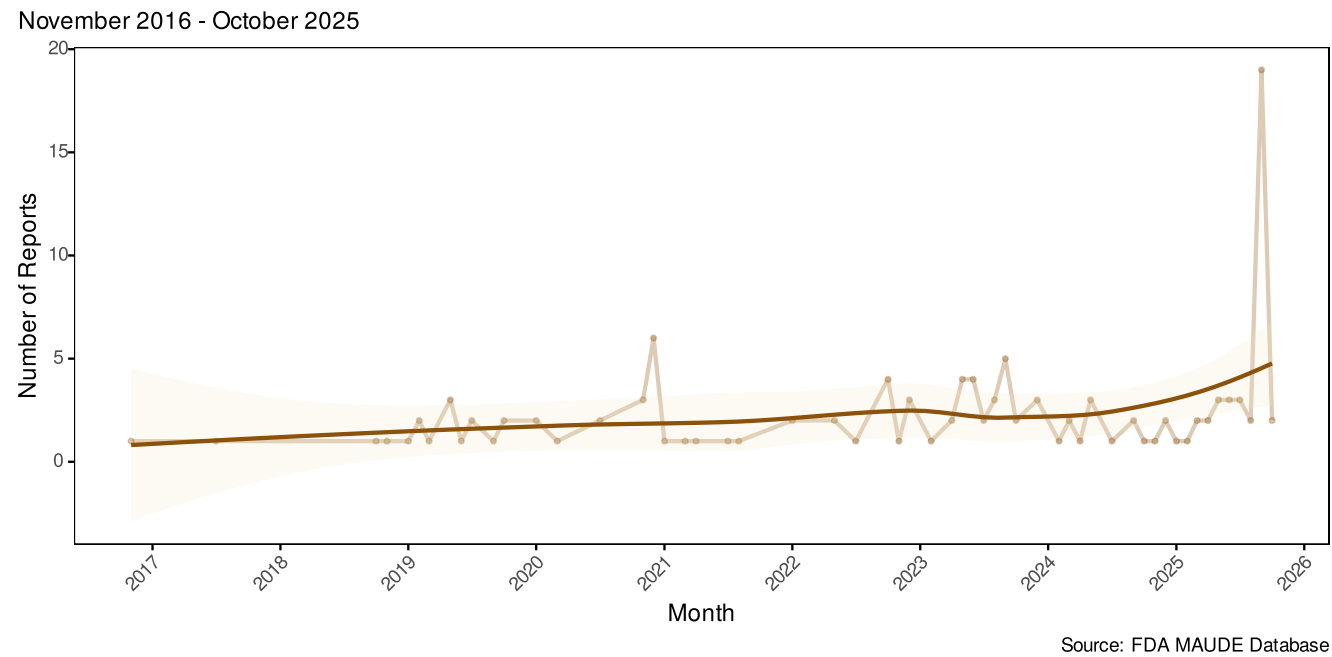
3.1. Overall Reporting Trends

Figure 1: Monthly trend of FDA MAUDE reports

3.2. Statistical Trend Analysis

Reporting Variability: The average monthly reporting rate is **2.3** reports (SD = **2.5**, CV = **112%**).

Statistically Significant Peaks (≥2 SD above mean, $p < 0.05$):

1 month(s) identified:

- **September 2025**: 19 reports (z=6.59, +737.8%)
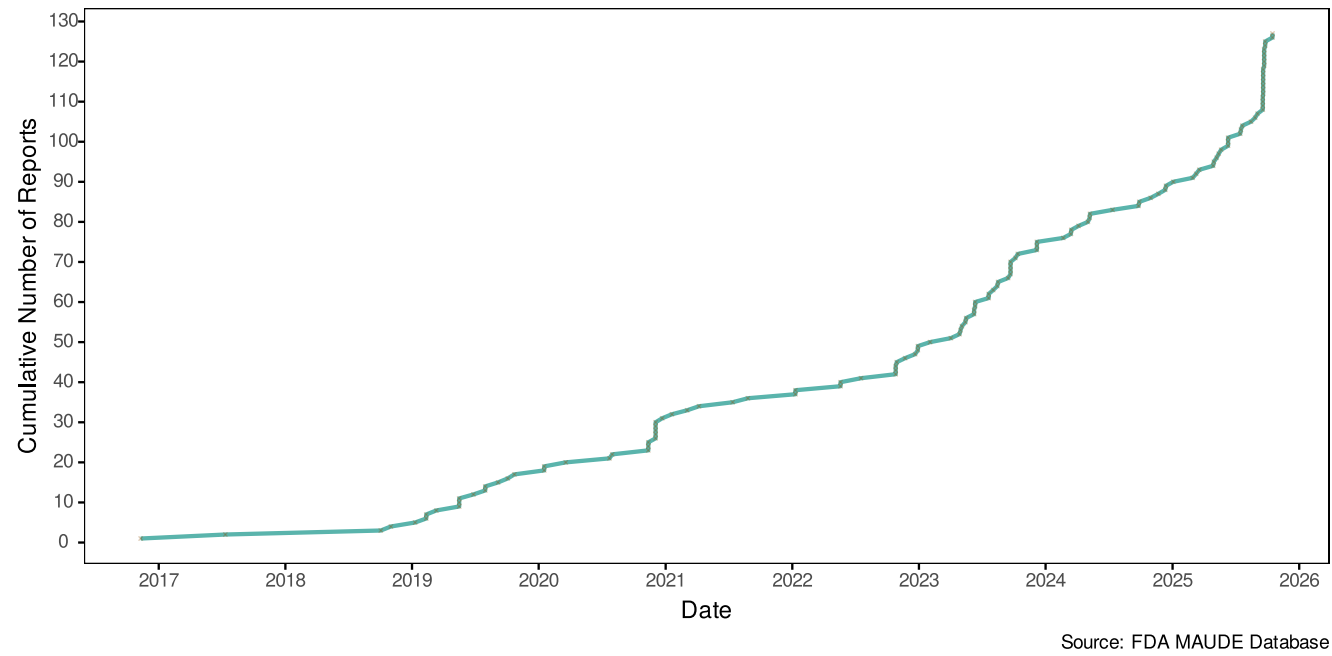
3.3. Cumulative Reports Over Time

Figure 2: Cumulative FDA MAUDE reports over time

4. Product Problem Analysis

4.1. Product Problems Analysis
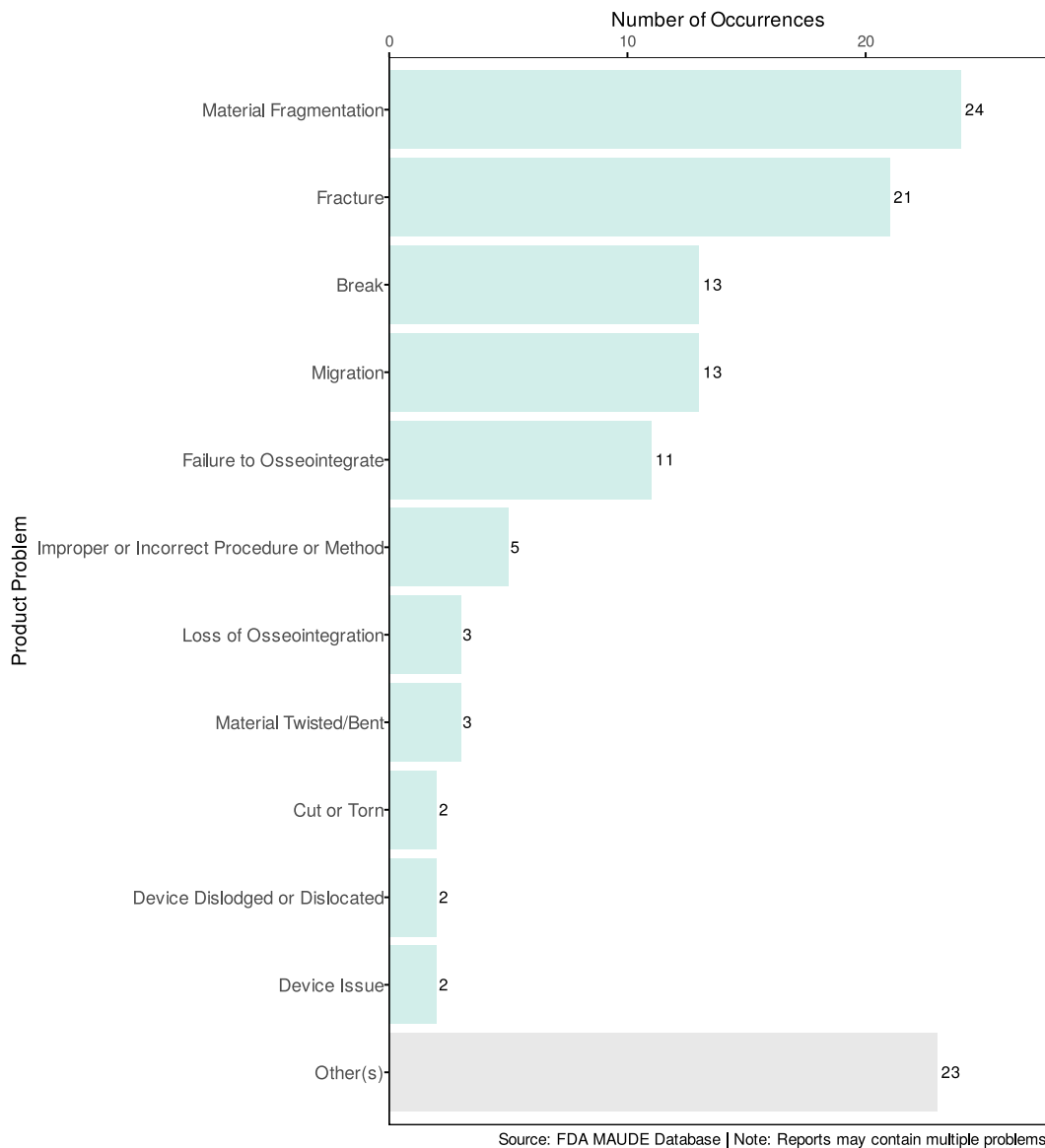
(November 2016 - October 2025)

Figure 3: Product problems representing 81.1% of problem occurrences, plus Other(s) category

A total of **11** product problem type(s) account for **81.1%** of all reported problem occurrences (**99** occurrences).

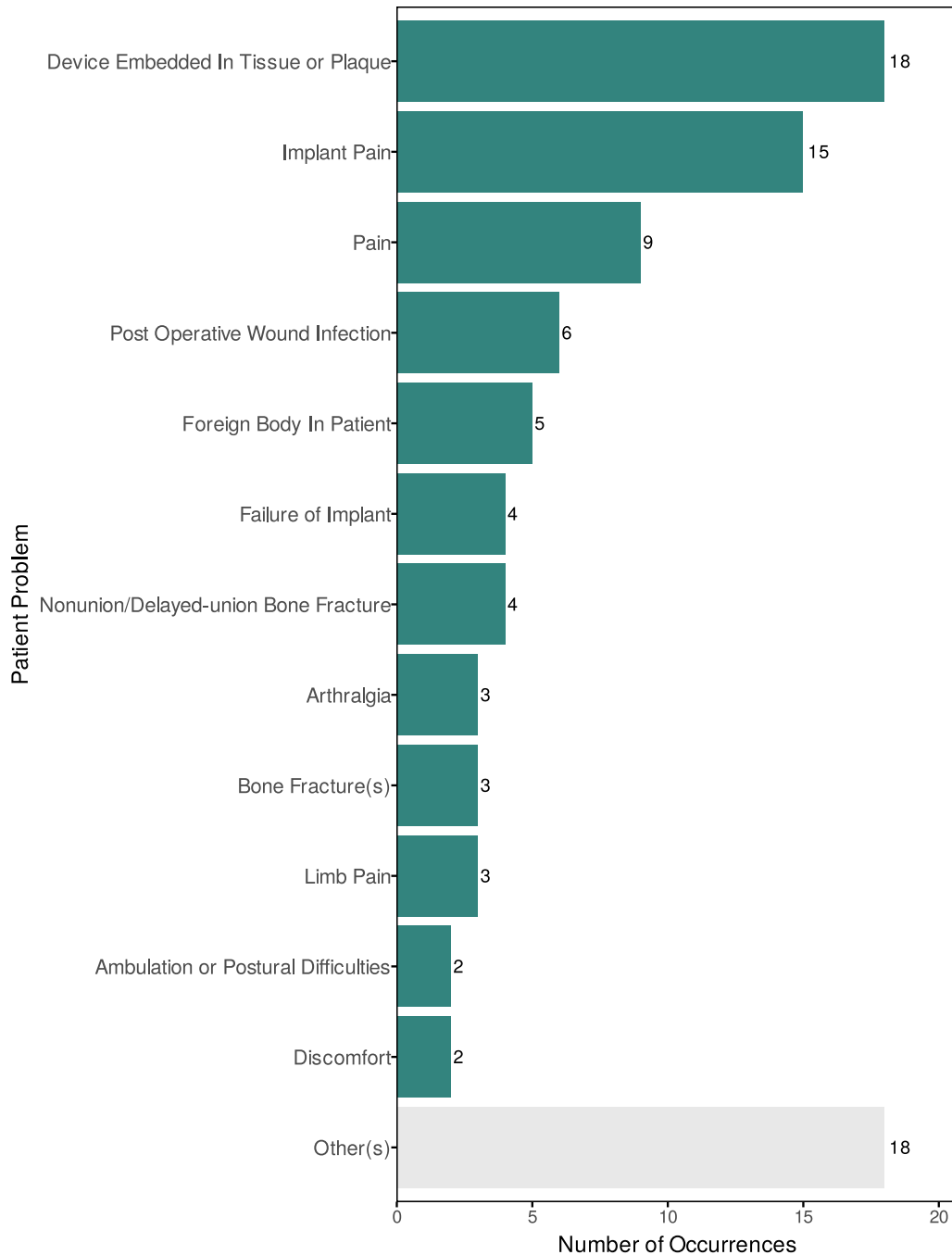The remaining **23** problem occurrences (**18.9%**) are categorized as "Other(s)".

All Product Problems Representing 81.1% of Data:

1. **Material Fragmentation** - 24 occurrences (19.7%)
2. **Fracture** - 21 occurrences (17.2%)
3. **Break** - 13 occurrences (10.7%)
4. **Migration** - 13 occurrences (10.7%)
5. **Failure to Osseointegrate** - 11 occurrences (9.0%)
6. **Improper or Incorrect Procedure or Method** - 5 occurrences (4.1%)
7. **Loss of Osseointegration** - 3 occurrences (2.5%)
8. **Material Twisted/Bent** - 3 occurrences (2.5%)
9. **Cut or Torn** - 2 occurrences (1.6%)
10. **Device Dislodged or Dislocated** - 2 occurrences (1.6%)
11. **Device Issue** - 2 occurrences (1.6%)

5. Patient Problem Analysis

5.1. Patient Problems Analysis

Clinical outcomes and adverse events

Figure 4: Patient problems representing 80.4% of problem occurrences, plus Other(s) category

A total of **12** patient problem type(s) account for **80.4%** of all reported patient problem occurrences (**74** occurrences).

The remaining **18** problem occurrences (**19.6%**) are categorized as "Other(s)".

All Patient Problems Representing 80.4% of Data:

1. **Device Embedded In Tissue or Plaque** - 18 occurrences (19.6%)
2. **Implant Pain** - 15 occurrences (16.3%)
3. **Pain** - 9 occurrences (9.8%)
4. **Post Operative Wound Infection** - 6 occurrences (6.5%)
5. **Foreign Body In Patient** - 5 occurrences (5.4%)
6. **Failure of Implant** - 4 occurrences (4.3%)
7. **Nonunion/Delayed-union Bone Fracture** - 4 occurrences (4.3%)
8. **Arthralgia** - 3 occurrences (3.3%)
9. **Bone Fracture(s)** - 3 occurrences (3.3%)
10. **Limb Pain** - 3 occurrences (3.3%)
11. **Ambulation or Postural Difficulties** - 2 occurrences (2.2%)
12. **Discomfort** - 2 occurrences (2.2%)

6. Manufacturer Analysis

6.1. Top Manufacturers
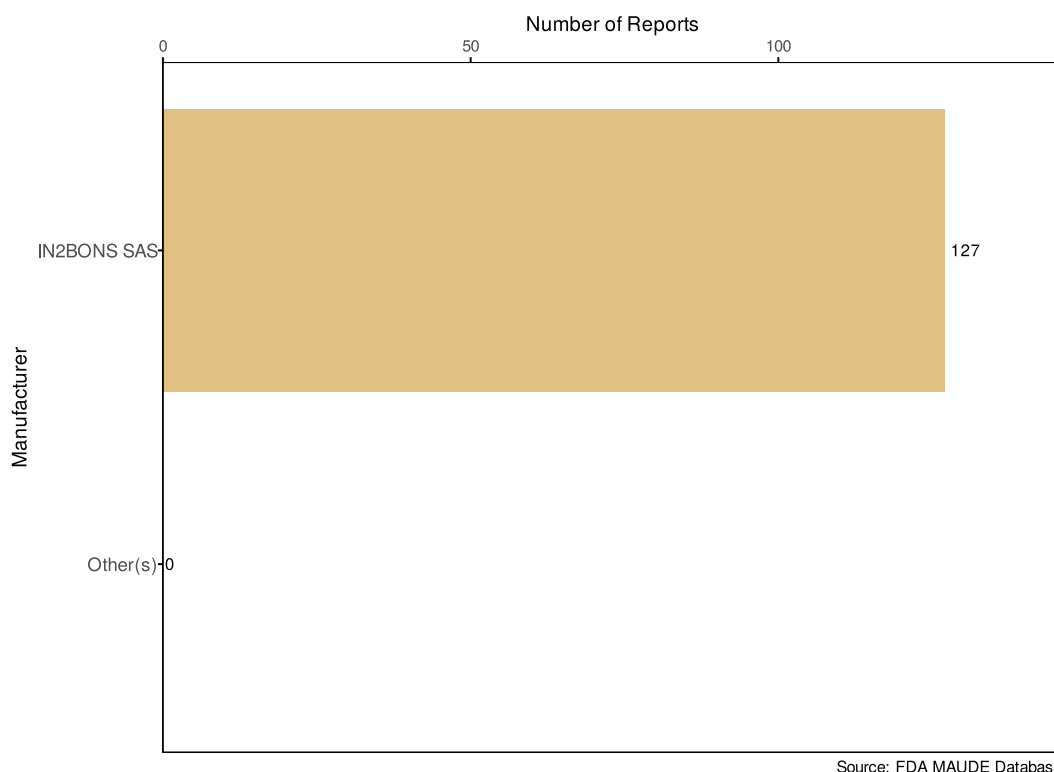
Figure 5: Manufacturers representing 100% of reports, plus Other(s) category

A total of **1** manufacturer(s) account for **100%** of all reports (**127** reports).

The top manufacturer, **IN2BONS SAS**, accounts for **127** reports (**100%** of total).

Table 2: Manufacturer(s) representing 100% of reports

Rank	Manufacturer	Reports	% of Total
1	IN2BONS SAS	127	100.00%

7. Device Brand Analysis
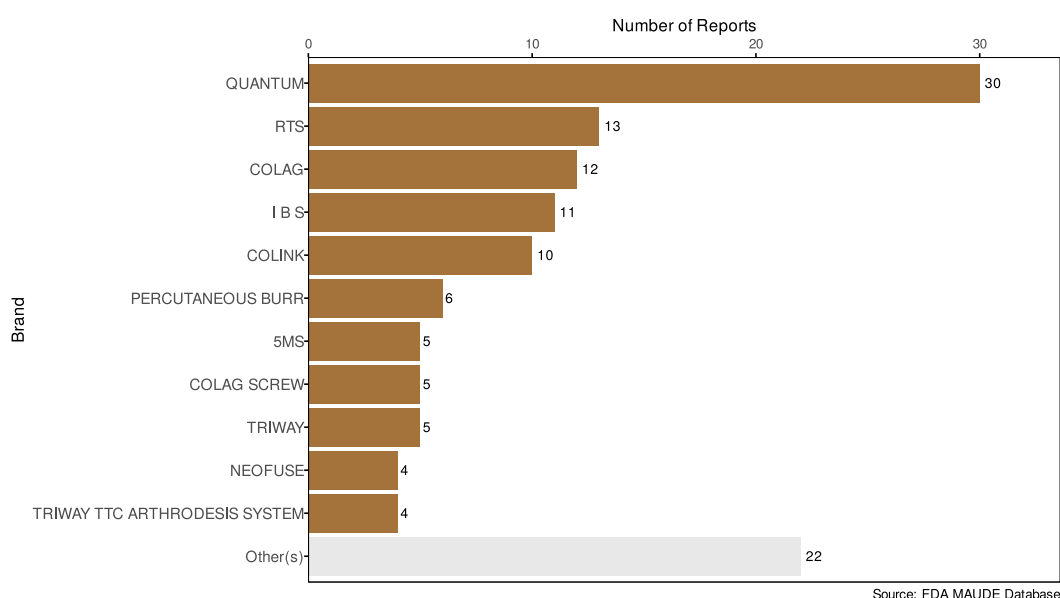
7.1. Top Device Brands

Figure 6: Device brands representing 82.7% of reports, plus Other(s) category

A total of **11** device brand(s) account for **82.7%** of all reports (**105** reports).

The remaining **22** reports (**17.3%**) are from other brands.

The top device brand, **QUANTUM**, accounts for **30** reports (**23.6%** of total).

Table 3: Device brand(s) representing 82.7% of reports

Rank	Brand	Reports	% of Total
1	QUANTUM	30	23.62%
2	RTS	13	10.24%
3	COLAG	12	9.45%
4	I B S	11	8.66%
5	COLINK	10	7.87%
6	PERCUTANEOUS BURR	6	4.72%
7	5MS	5	3.94%
8	COLAG SCREW	5	3.94%
9	TRIWAY	5	3.94%
10	NEOFUSE	4	3.15%
11	TRIWAY TTC ARTHRODESIS SYSTEM	4	3.15%

7.2. Brand Temporal Trends
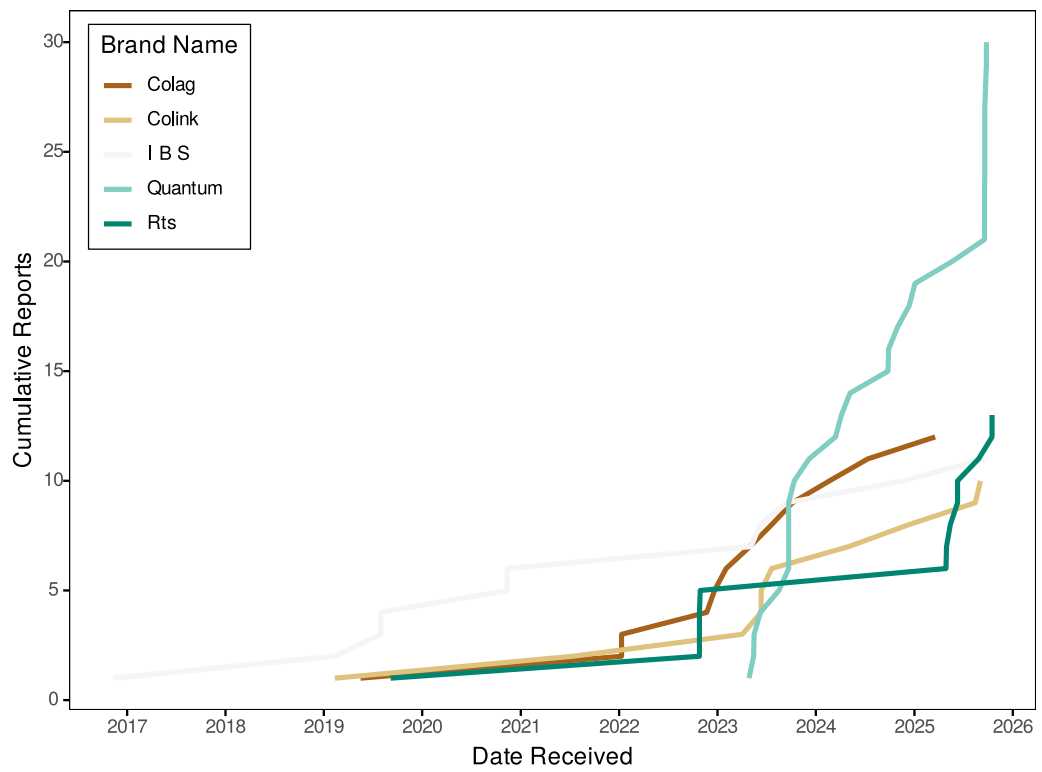
Figure 7: Cumulative adverse event reports by top 5 brands

8. Technical Appendix

8.1. Data Source

- **Database**: OpenFDA Medical Device Adverse Events
- **API Access**: https://open.fda.gov/apis/device/event/

8.2. Analysis Tools

- **Python 3.x** with pandas and rapidfuzz for data processing
- **R** with tidyverse, ggplot2, and lubridate for visualization
- **Fuzzy Matching**: RapidFuzz library for text standardization
- **Visualization**: ggplot2 with custom base R theme
- **Report Generation**: Quarto for reproducible analytics

8.3. Detailed Methodology

8.3.1. Fuzzy Matching Algorithm

Algorithm: The analysis uses the Levenshtein distance algorithm, which calculates the minimum number of single-character edits (insertions, deletions, or substitutions) needed to transform one string into another.

Implementation: The RapidFuzz library implements partial ratio matching, which finds the best matching substring and calculates similarity as a percentage (0-100%).

Matching Process: 1. Text is normalized: converted to uppercase, special characters removed, whitespace standardized 2. Similarity scores are calculated between all name pairs 3. Names with ≥75% similarity are grouped together 4. The shortest variant in each group becomes the canonical name

Example: "MEDTRONIC INC", "Medtronic Inc.", and "MEDTRONIC" would all be grouped under "MEDTRONIC" (shortest variant).

8.3.2. Concentration-Based Analysis

Implementation Details: 1. Items are sorted by frequency (descending order) 2. Cumulative percentages are calculated for each item 3. Items are included if the *previous* item's cumulative percentage was below 80% 4. This ensures complete categories—no category is split between main analysis and "Other(s)"

Key Features: - The exact percentage may exceed 80% to maintain category integrity - All categories meeting the threshold are listed, not just a predetermined number - The "Other(s)" category provides perspective on the long-tail distribution

8.3.3. Statistical Methods

Variability Metrics: - **Standard Deviation (SD)**: Measures the typical spread of monthly reports around the average - **Coefficient of Variation (CV)**: Expresses SD as a percentage of the mean (CV = SD/Mean × 100) - **Interpretation**: CV < 15% = low variability, 15-30% = moderate, >30% = high variability

Outlier Detection: - **Z-scores**: Measure how many standard deviations each month's report count deviates from the mean - **Threshold**: Months with |z-score| ≥ 2 are flagged as statistically significant (p <

0.05) - **Interpretation**: Indicates unusually high (peaks) or low (valleys) reporting activity beyond ~95% of normal distribution

8.4. Exclusion Criteria

Patient Problems Excluded:

- No Code Available
- No Known Impact Or Consequence To Patient
- Symptoms or Conditions
- No Information
- No Consequences Or Impact To Patient
- Appropriate Clinical Signs
- No Clinical Signs
- Conditions Term / Code Not Available
- Appropriate Term / Code Not Available
- Insufficient Information
- No Patient Involvement
- Reaction
- Patient Problem/Medical Problem

Product Problems Excluded:

- Adverse Event Without Identified Device or Use Problem
- Appropriate Term/Code Not Available
- Appropriate Term / Code Not Available
- Unknown (for use when the device problem is not known)
- Insufficient Information
- No Apparent Adverse Event

8.5. Report Metadata

- **Generated**: 2025-11-20 13:20:28
- **Dataset Version**: 2025-10-16
- **Total Records Analyzed**: 127
- **Analysis Pipeline**: OpenFDA Medical Device Adverse Event Analysis v2.1

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