

OPENFDA MEDICAL DEVICE ADVERSE EVENT ANALYSIS

Analysis of FDA Medical Device Adverse Event Reports

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1. Executive Summary

This report analyzes **3,552** FDA medical device adverse event reports submitted between **April 28, 2000** and **October 31, 2025** (a period of **306.1** months). The dataset includes **37** unique manufacturers and **233** unique device brands. The average reporting rate was **18.1** reports per month, with peak reporting of **314** reports in **March 2020**.

Table 1: Summary statistics of FDA MAUDE reports

| Metric | Value |
|-------------------------|------------------------------------|
| Total Reports | 3,552 |
| Date Range | April 28, 2000 to October 31, 2025 |
| Reporting Duration | 9317 days (306.1 months) |
| Unique Manufacturers | 37 |
| Unique Device Brands | 233 |
| Average Monthly Reports | 18.1 reports/month |
| Maximum Monthly Reports | 314 reports in March 2020 |

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

The analysis employs fuzzy matching algorithms to standardize manufacturer and brand names, addressing inconsistencies in naming conventions across reports. This standardization process uses the **RapidFuzz** library with partial ratio matching to group similar names under a canonical representation.

2.3. Problem Classification

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

3. Temporal Trend Analysis

3.1. Overall Reporting Trends

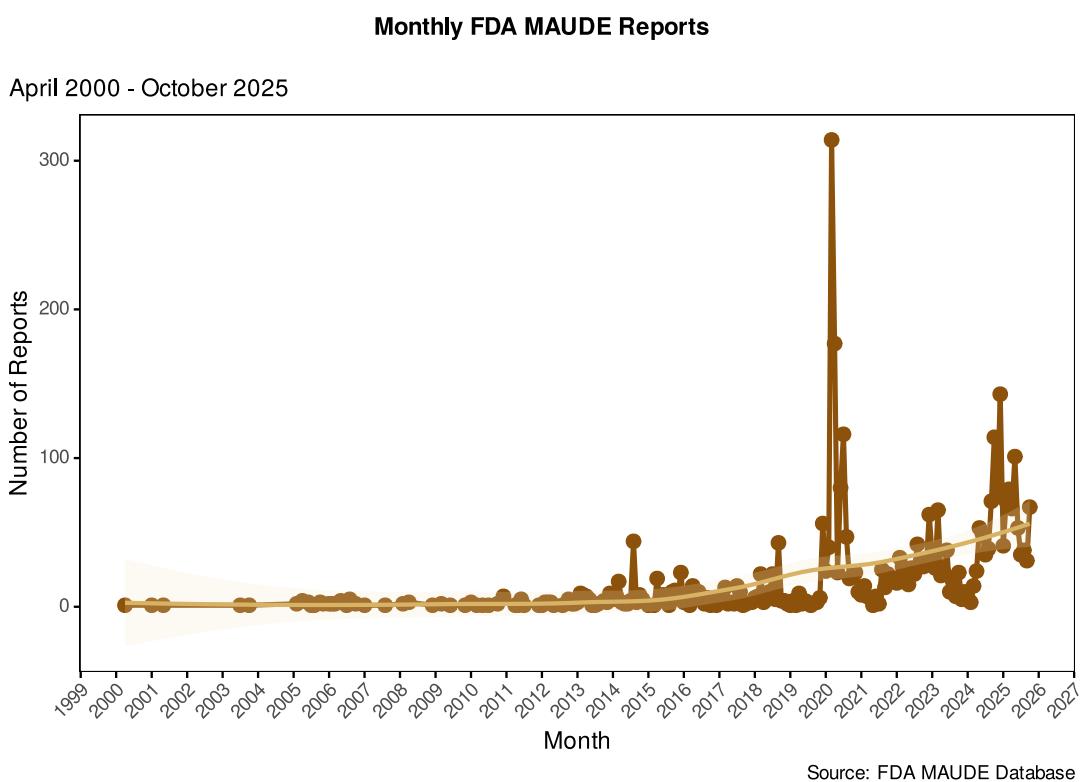


Figure 1: Monthly trend of FDA MAUDE reports

i Trend Observation

The reporting shows variability across months, with notable peaks in March 2020, April 2020, December 2024, July 2020, October 2024, May 2025, June 2020, March 2025, November 2024, September 2024, February 2025, October 2025, April 2025, March 2023, December 2022, December 2019, May 2024, June 2025, June 2024, August 2020, August 2014, September 2018, August 2022, January 2025, February 2020, August 2024, June 2023, August 2025, July 2024, July 2025, January 2023, February 2022, September 2025, September 2022, November 2022, March 2022, October 2022, June 2022, February 2023, August 2021, January 2020, April 2024, December 2015, May 2020, November 2020, May 2023, October 2023. The average monthly reporting rate is 18.1 reports, with a standard deviation of 33.5 reports.

3.2. Cumulative Reports Over Time

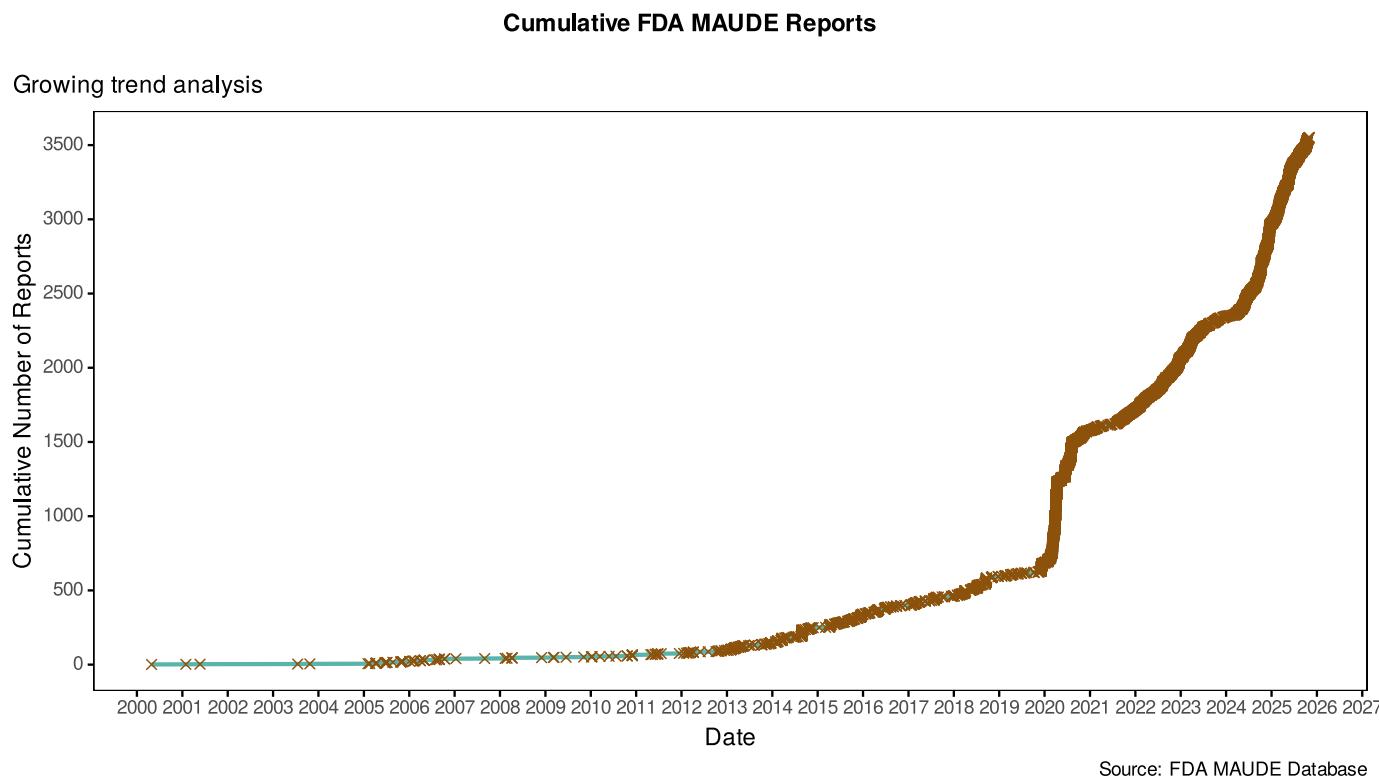


Figure 2: Cumulative FDA MAUDE reports over time

4. Product Problem Analysis

4.1. Product Problems Analysis (80% of Data)

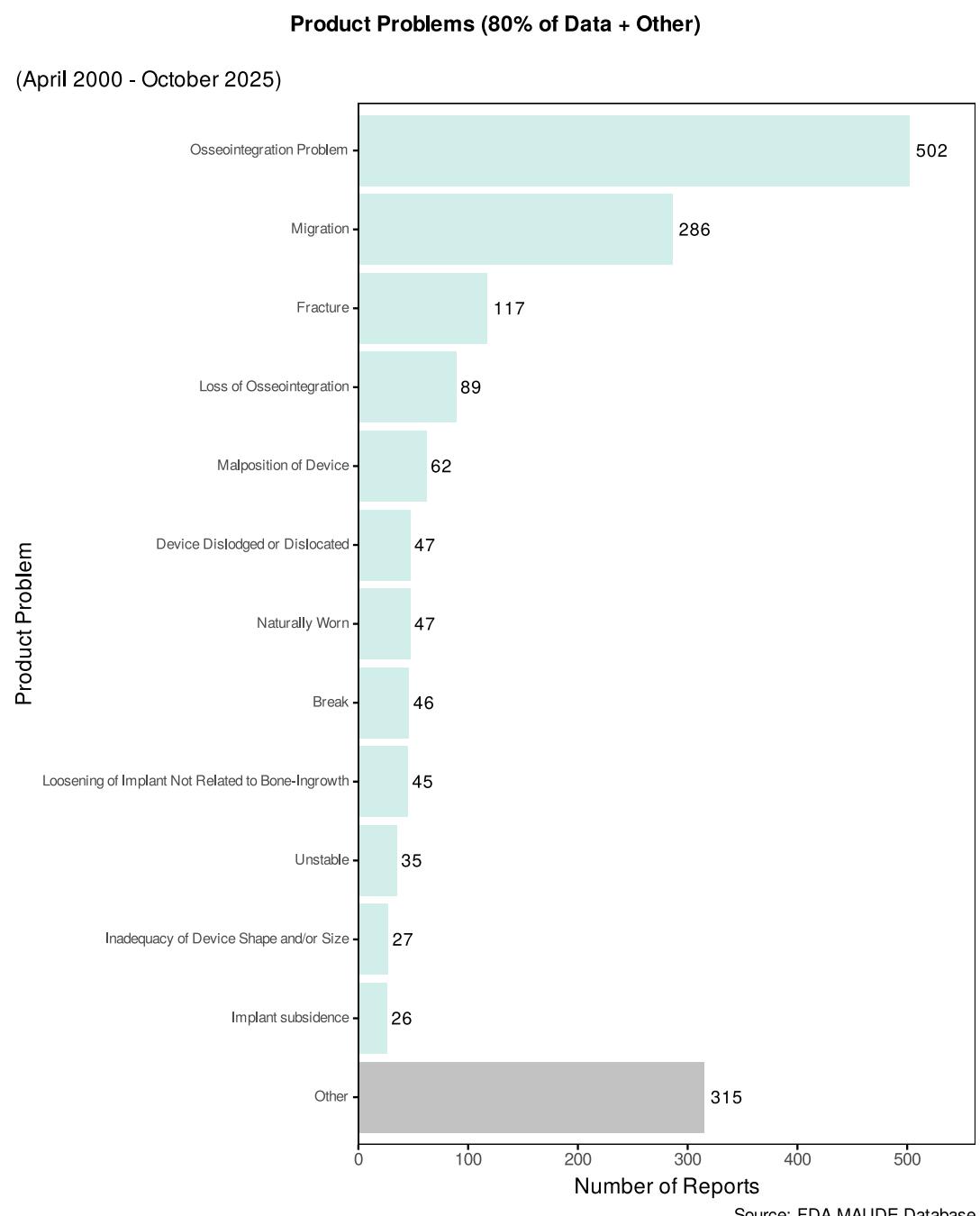


Figure 3: Product problems accounting for 80% of reports, plus 'Other' category

Product Issues - 80% Analysis

12 product problem types account for **80%** of all reported issues (**1329** reports, **37.4%** of total).

The remaining **315** reports (**8.9%**) are categorized as “Other”.

All Product Problems in 80% Threshold:

1. **Osseointegration Problem** - 502 reports (14.1%)
2. **Migration** - 286 reports (8.1%)
3. **Fracture** - 117 reports (3.3%)
4. **Loss of Osseointegration** - 89 reports (2.5%)
5. **Malposition of Device** - 62 reports (1.7%)
6. **Device Dislodged or Dislocated** - 47 reports (1.3%)
7. **Naturally Worn** - 47 reports (1.3%)
8. **Break** - 46 reports (1.3%)
9. **Loosening of Implant Not Related to Bone-Ingrowth** - 45 reports (1.3%)
10. **Unstable** - 35 reports (1.0%)
11. **Inadequacy of Device Shape and/or Size** - 27 reports (0.8%)
12. **Implant subsidence** - 26 reports (0.7%)

5. Patient Problem Analysis

5.1. Patient Problems Analysis (80% of Data)

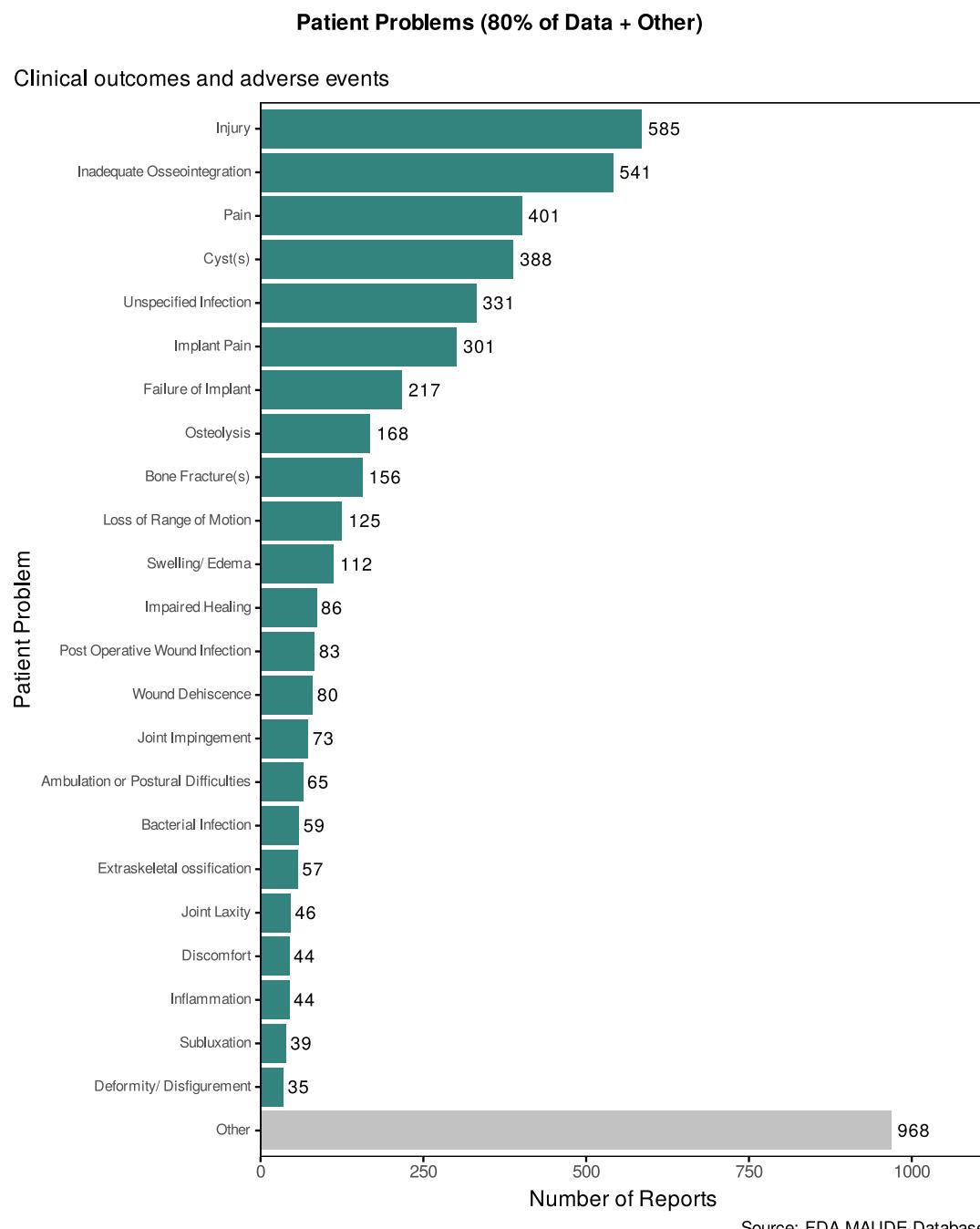


Figure 4: Patient problems accounting for 80% of reports, plus ‘Other’ category

i Patient Problems - 80% Analysis

23 patient problem types account for **80%** of all reported patient issues (**4036** reports, **113.6%** of total).

The remaining **968** reports (**27.3%**) are categorized as “Other”.

All Patient Problems in 80% Threshold:

1. **Injury** - 585 reports (16.5%)
2. **Inadequate Osseointegration** - 541 reports (15.2%)
3. **Pain** - 401 reports (11.3%)
4. **Cyst(s)** - 388 reports (10.9%)
5. **Unspecified Infection** - 331 reports (9.3%)
6. **Implant Pain** - 301 reports (8.5%)
7. **Failure of Implant** - 217 reports (6.1%)
8. **Osteolysis** - 168 reports (4.7%)
9. **Bone Fracture(s)** - 156 reports (4.4%)
10. **Loss of Range of Motion** - 125 reports (3.5%)
11. **Swelling/ Edema** - 112 reports (3.2%)
12. **Impaired Healing** - 86 reports (2.4%)
13. **Post Operative Wound Infection** - 83 reports (2.3%)
14. **Wound Dehiscence** - 80 reports (2.3%)
15. **Joint Impingement** - 73 reports (2.1%)
16. **Ambulation or Postural Difficulties** - 65 reports (1.8%)
17. **Bacterial Infection** - 59 reports (1.7%)
18. **Extraskeletal ossification** - 57 reports (1.6%)
19. **Joint Laxity** - 46 reports (1.3%)
20. **Discomfort** - 44 reports (1.2%)
21. **Inflammation** - 44 reports (1.2%)
22. **Subluxation** - 39 reports (1.1%)
23. **Deformity/ Disfigurement** - 35 reports (1.0%)

6. Manufacturer Analysis

6.1. Top Manufacturers (80% of Data)

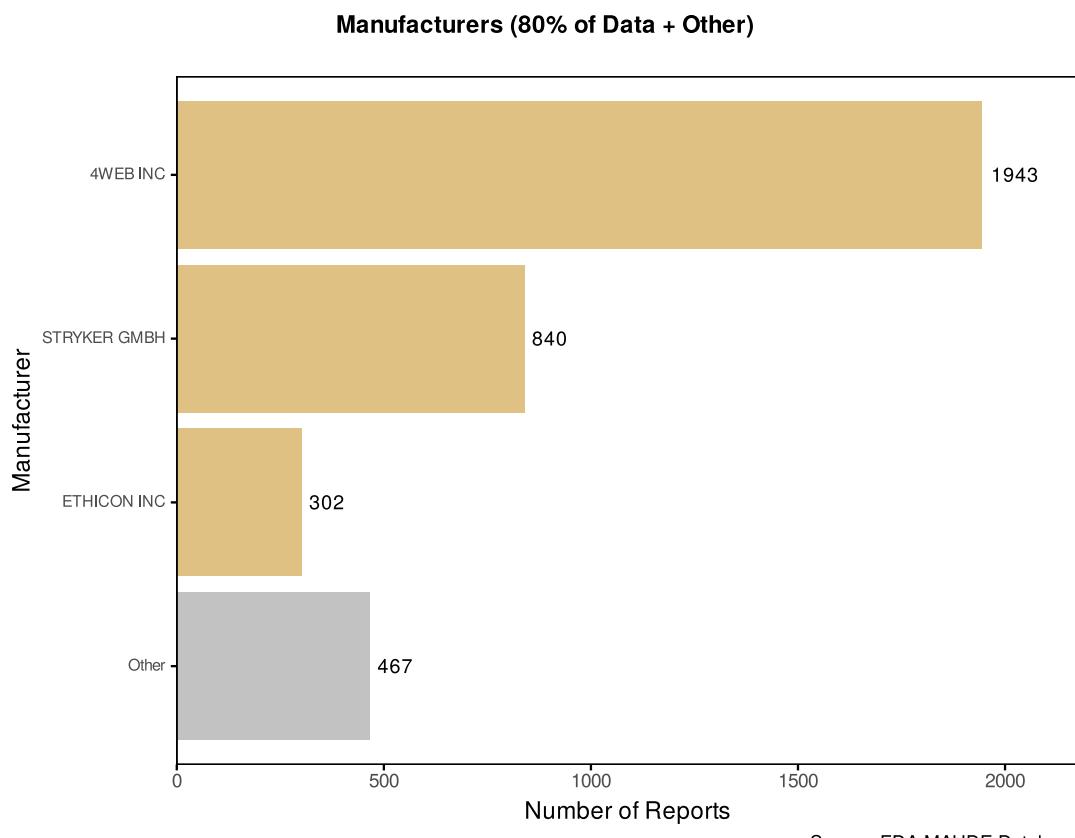


Figure 5: Manufacturers accounting for 80% of reports, plus ‘Other’ category

3 manufacturers account for **80%** of all reports (**3085** reports, **86.9%** of total).

The remaining **467** reports (**13.1%**) are from other manufacturers.

The top manufacturer, **4WEB INC**, accounts for **1943** reports (**54.7%** of total).

Table 2: Manufacturers accounting for 80% of reports

| Rank | Manufacturer | Reports | % of Total |
|------|--------------|---------|------------|
| 1 | 4WEB INC | 1,943 | 54.70% |
| 2 | STRYKER GMBH | 840 | 23.65% |
| 3 | ETHICON INC | 302 | 8.50% |

7. Device Brand Analysis

7.1. Top Device Brands (80% of Data)

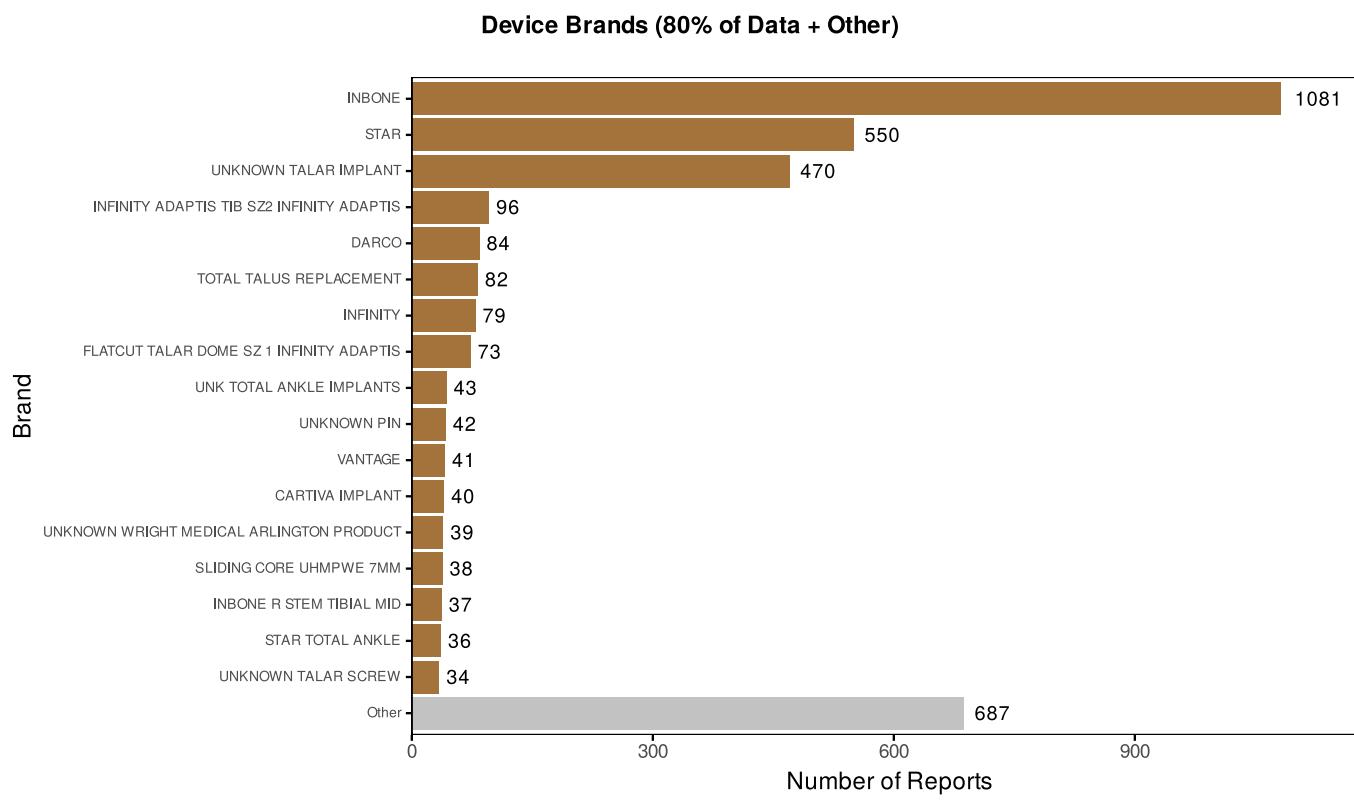


Figure 6: Device brands accounting for 80% of reports, plus 'Other' category

17 device brands account for **80%** of all reports (**2865** reports, **80.7%** of total).

The remaining **687** reports (**19.3%**) are from other brands.

The top device brand, **INBONE**, accounts for **1081** reports (**30.4%** of total).

Table 3: Device brands accounting for 80% of reports

| Rank | Brand | Reports | % of Total |
|------|---|---------|------------|
| 1 | INBONE | 1,081 | 30.43% |
| 2 | STAR | 550 | 15.48% |
| 3 | UNKNOWN TALAR IMPLANT | 470 | 13.23% |
| 4 | INFINITY ADAPTIS TIB SZ2 INFINITY ADAPTIS | 96 | 2.70% |
| 5 | DARCO | 84 | 2.36% |
| 6 | TOTAL TALUS REPLACEMENT | 82 | 2.31% |
| 7 | INFINITY | 79 | 2.22% |
| 8 | FLATCUT TALAR DOME SZ 1 INFINITY ADAPTIS | 73 | 2.06% |
| 9 | UNK TOTAL ANKLE IMPLANTS | 43 | 1.21% |
| 10 | UNKNOWN PIN | 42 | 1.18% |
| 11 | VANTAGE | 41 | 1.15% |
| 12 | CARTIVA IMPLANT | 40 | 1.13% |
| 13 | UNKNOWN WRIGHT MEDICAL ARLINGTON PRODUCT | 39 | 1.10% |
| 14 | SLIDING CORE UHMPWE 7MM | 38 | 1.07% |
| 15 | INBONE R STEM TIBIAL MID | 37 | 1.04% |
| 16 | STAR TOTAL ANKLE | 36 | 1.01% |
| 17 | UNKNOWN TALAR SCREW | 34 | 0.96% |

7.2. Brand Temporal Trends

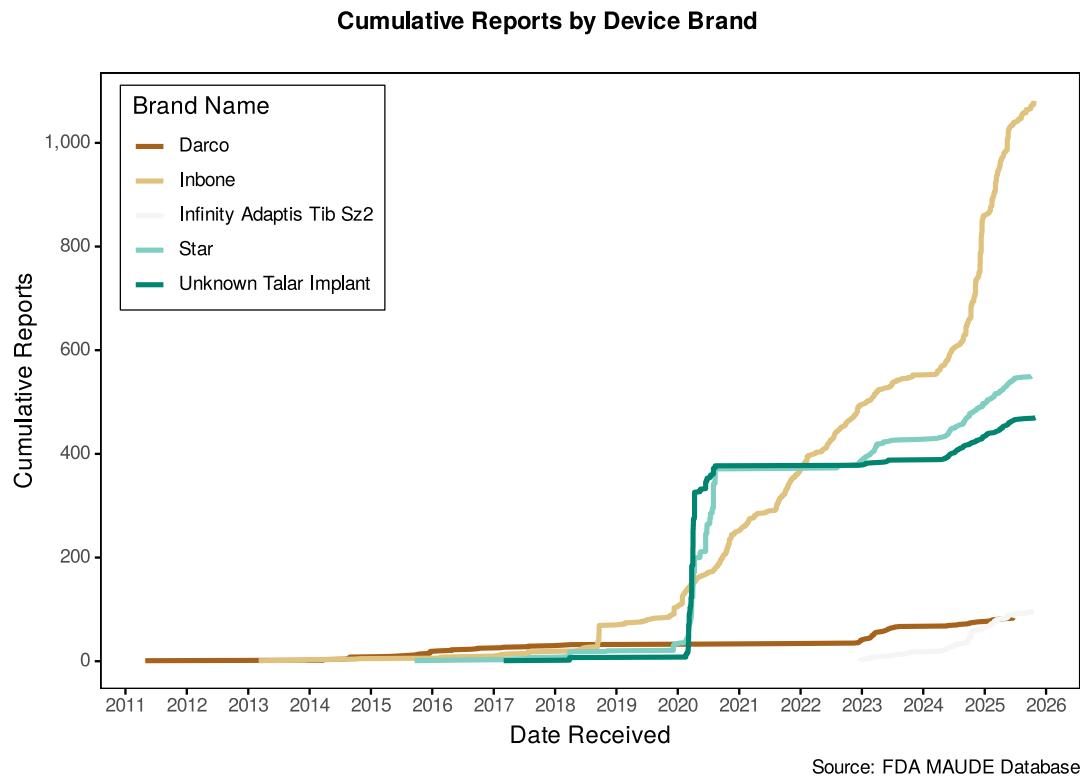


Figure 7: Cumulative adverse event reports by top 5 brands

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. Exclusion Criteria

Patient Problems Excluded:

No Code Available, No Known Impact, Symptoms or Conditions,
No Information, No Consequences, Insufficient Information

Product Problems Excluded:

Adverse Event Without Identified Device, No Apparent Adverse Event,
Appropriate Term/Code Not Available, Unknown, Insufficient Information

8.4. Report Metadata

- **Generated:** 2025-11-19 17:26:42
- **Dataset Version:** 2025-10-31
- **Total Records Analyzed:** 3,552
- **Analysis Pipeline:** OpenFDA Medical Device Adverse Event Analysis v2.1

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