OPENFDA MEDICAL DEVICE ADVERSE EVENT ANALYSIS

Analysis of FDA Medical Device Adverse Event Reports

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1. Executive Summary

This report analyzes **268** FDA medical device adverse event reports submitted between **August 25, 2024** and **October 29, 2025** (a period of **14.1** months). The dataset includes **1** unique manufacturers and **10** unique device brands. The average reporting rate was **22.3** reports per month, with peak reporting of **68** reports in **September 2025**.

Table 1: Summary statistics of FDA MAUDE reports

Metric	Value
Total Reports	268
Date Range	August 25, 2024 to October 29, 2025
Reporting Duration	430 days (14.1 months)
Unique Manufacturers	1
Unique Device Brands	10
Average Monthly Reports	22.3 reports/month
Maximum Monthly Reports	68 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

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
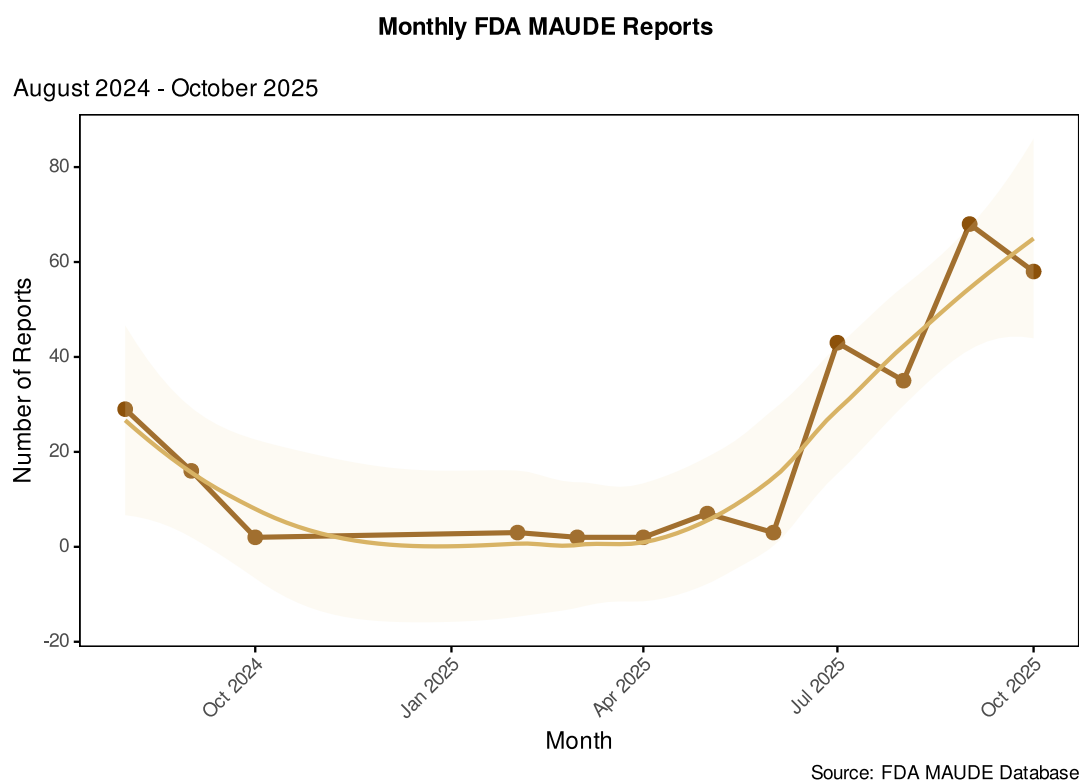
3.1. Overall Reporting Trends

Monthly FDA MAUDE Reports

August 2024 - October 2025

Source: FDA MAUDE Database

Figure 1: Monthly trend of FDA MAUDE reports

ⓘ Statistical Trend Analysis

Reporting Variability: The average monthly reporting rate is **22.3** reports (SD = **23.8**, CV = **106.8%**).

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

No statistically significant peaks detected at 95% confidence level.

Statistically Significant Valleys (≥2 SD below mean, $p < 0.05$):

No statistically significant valleys detected at 95% confidence level.

Note: Months are considered statistically significant outliers when they deviate by ≥2 standard deviations from the mean (z-score ≥ |2|), corresponding to approximately 95% confidence level.
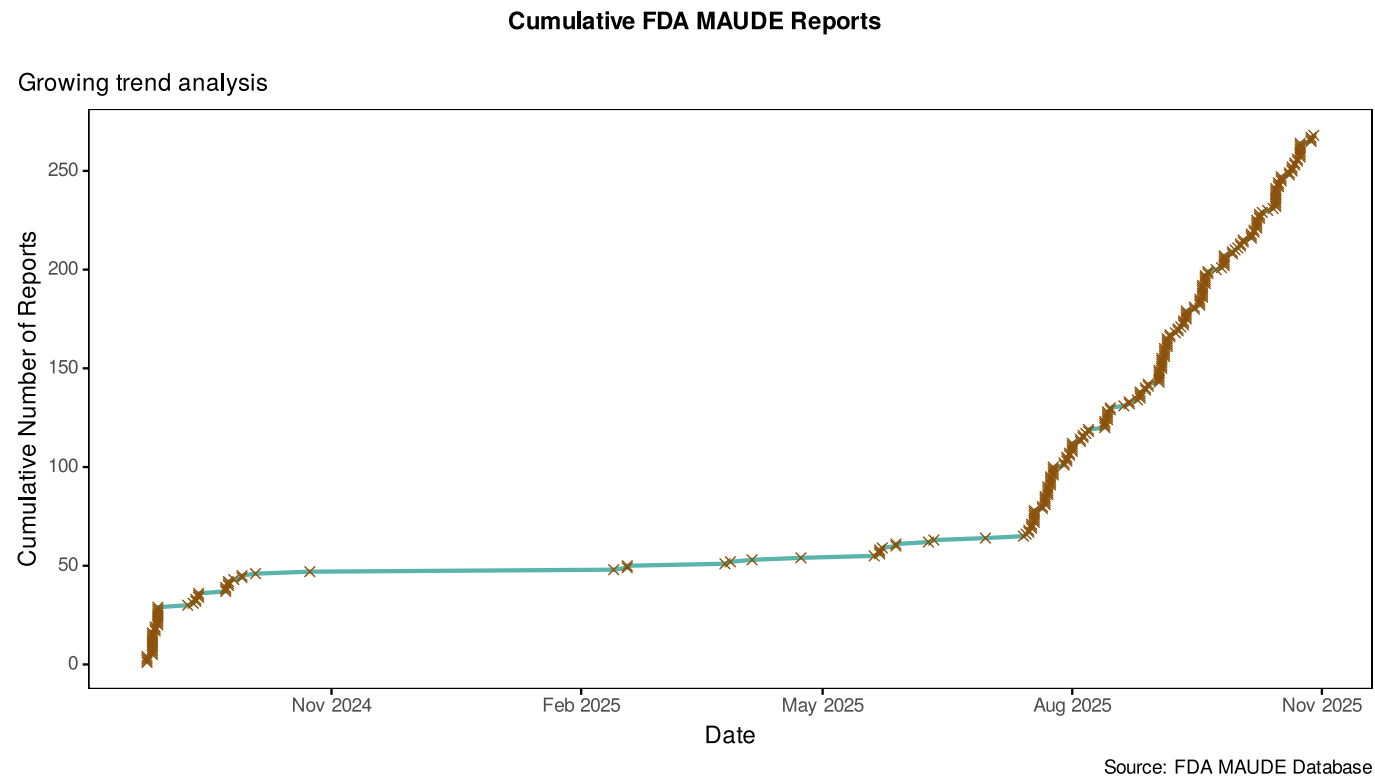
3.2. Cumulative Reports Over Time

Cumulative FDA MAUDE Reports

Growing trend analysis

Source: FDA MAUDE Database

Figure 2: Cumulative FDA MAUDE reports over time

4. Product Problem Analysis

4.1. Product Problems Analysis (80% of Data)

Product Problems (80% of Data + Other)
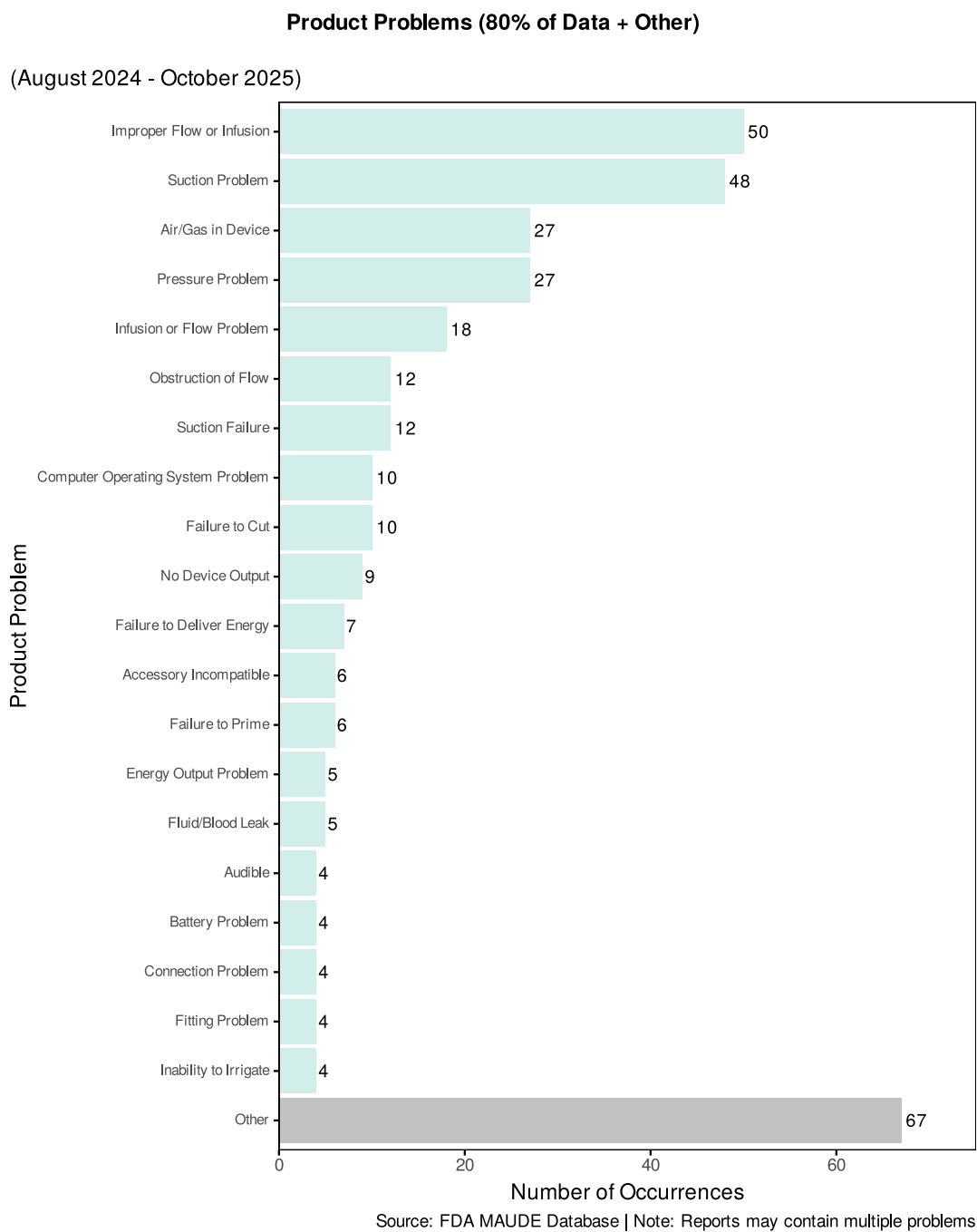
(August 2024 - October 2025)

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

⚠ Product Issues - 80% Analysis

A total of **20** product problem types account for **80%** of all reported problem occurrences (**272** occurrences, **80.2%** of total).

The remaining **67** problem occurrences (**19.8%**) are categorized as "Other".

Note: Individual reports may list multiple product problems, so total occurrences may exceed the number of reports.

All Product Problems in 80% Threshold:

1. **Improper Flow or Infusion** - 50 occurrences (14.7%)
2. **Suction Problem** - 48 occurrences (14.2%)
3. **Air/Gas in Device** - 27 occurrences (8.0%)
4. **Pressure Problem** - 27 occurrences (8.0%)
5. **Infusion or Flow Problem** - 18 occurrences (5.3%)
6. **Obstruction of Flow** - 12 occurrences (3.5%)
7. **Suction Failure** - 12 occurrences (3.5%)
8. **Computer Operating System Problem** - 10 occurrences (2.9%)
9. **Failure to Cut** - 10 occurrences (2.9%)
10. **No Device Output** - 9 occurrences (2.7%)
11. **Failure to Deliver Energy** - 7 occurrences (2.1%)
12. **Accessory Incompatible** - 6 occurrences (1.8%)
13. **Failure to Prime** - 6 occurrences (1.8%)
14. **Energy Output Problem** - 5 occurrences (1.5%)
15. **Fluid/Blood Leak** - 5 occurrences (1.5%)
16. **Audible** - 4 occurrences (1.2%)
17. **Battery Problem** - 4 occurrences (1.2%)
18. **Connection Problem** - 4 occurrences (1.2%)
19. **Fitting Problem** - 4 occurrences (1.2%)
20. **Inability to Irrigate** - 4 occurrences (1.2%)

5. Patient Problem Analysis

5.1. Patient Problems Analysis (80% of Data)

Patient Problems (80% of Data + Other)
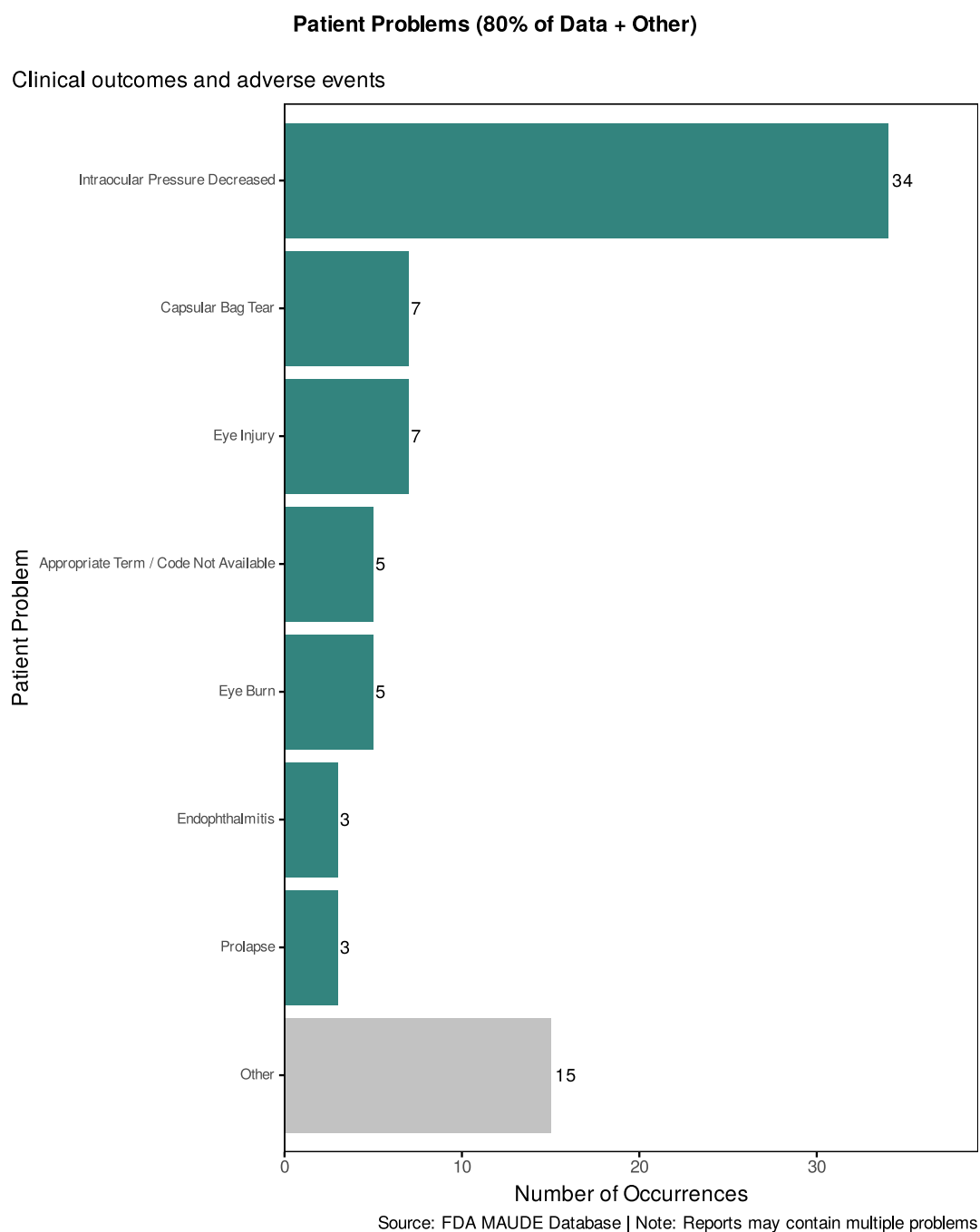
Clinical outcomes and adverse events

Figure 4: Patient problems accounting for 80% of problem occurrences, plus 'Other' category

i Patient Problems - 80% Analysis

A total of **7** patient problem types account for **80%** of all reported patient problem occurrences (**64** occurrences, **81%** of total).

The remaining **15** problem occurrences (**19%**) are categorized as "Other".

Note: Individual reports may list multiple patient problems, so total occurrences may exceed the number of reports.

All Patient Problems in 80% Threshold:

1. **Intraocular Pressure Decreased** - 34 occurrences (43.0%)
2. **Capsular Bag Tear** - 7 occurrences (8.9%)
3. **Eye Injury** - 7 occurrences (8.9%)
4. **Appropriate Term / Code Not Available** - 5 occurrences (6.3%)
5. **Eye Burn** - 5 occurrences (6.3%)
6. **Endophthalmitis** - 3 occurrences (3.8%)
7. **Prolapse** - 3 occurrences (3.8%)

6. Manufacturer Analysis

6.1. Top Manufacturers (80% of Data)
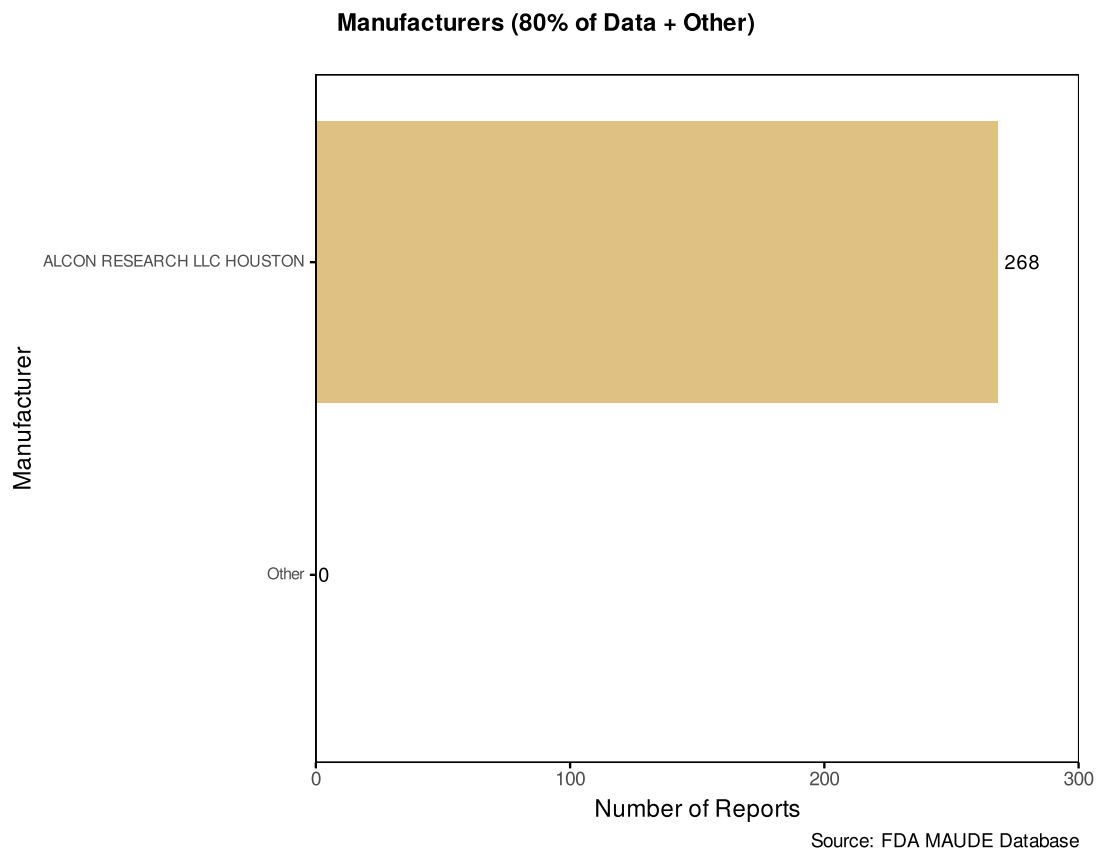
Manufacturers (80% of Data + Other)

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

A total of **1** manufacturers account for **80%** of all reports (**268** reports, **100%** of total).

The remaining **0** reports (**0%**) are from other manufacturers.

The top manufacturer, **ALCON RESEARCH LLC HOUSTON**, accounts for **268** reports (**100%** of total).

Table 2: Manufacturers accounting for 80% of reports

Rank	Manufacturer	Reports	% of Total
1	ALCON RESEARCH LLC HOUSTON	268	100.00%

7. Device Brand Analysis

7.1. Top Device Brands (80% of Data)

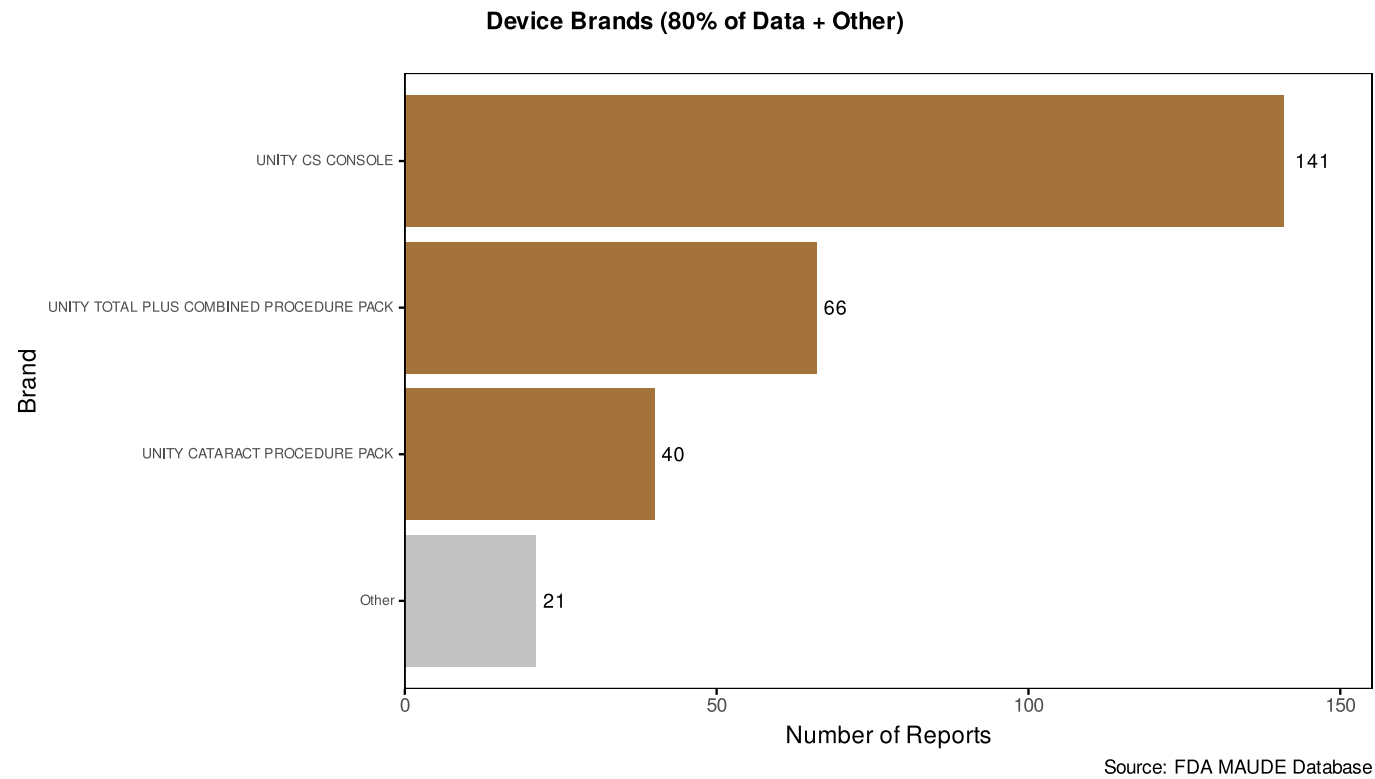**Device Brands (80% of Data + Other)**

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

A total of **3** device brands account for **80%** of all reports (**247** reports, **92.2%** of total).

The remaining **21** reports (**7.8%**) are from other brands.

The top device brand, **UNITY CS CONSOLE**, accounts for **141** reports (**52.6%** of total).

Table 3: Device brands accounting for 80% of reports

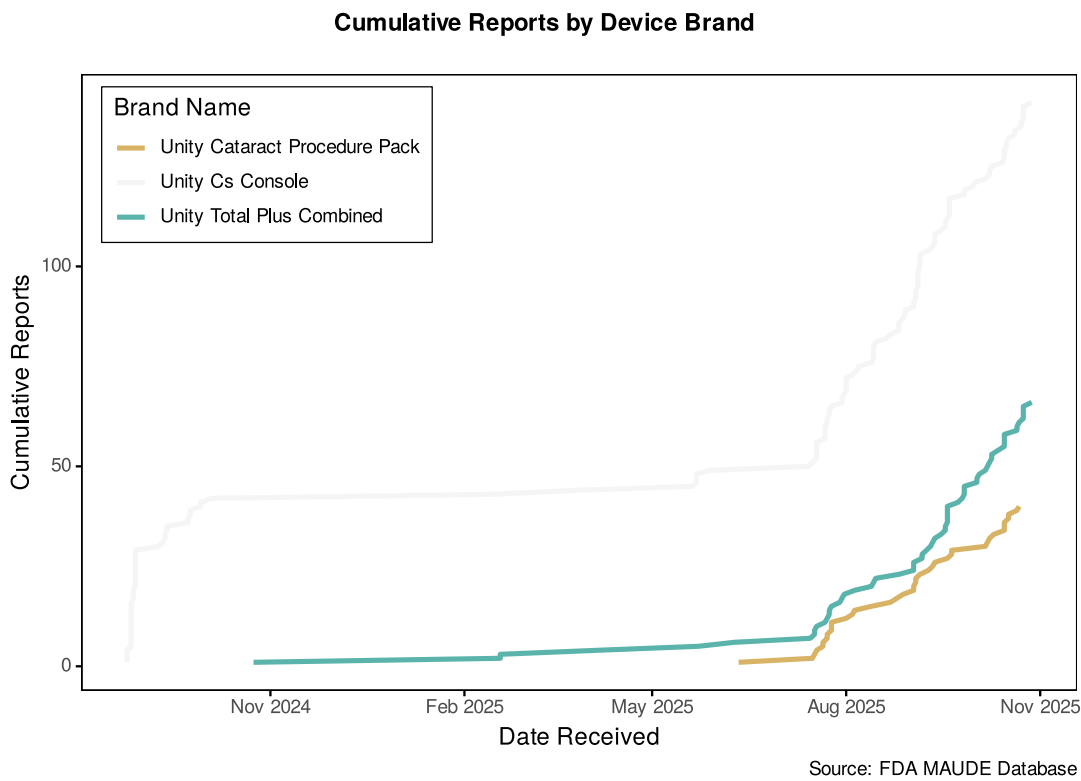| Rank	Brand	Reports	% of Total
1	UNITY CS CONSOLE	141	52.61%
2	UNITY TOTAL PLUS COMBINED PROCEDURE PACK	66	24.63%
3	UNITY CATARACT PROCEDURE PACK	40	14.93%

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 17:41:01
- **Dataset Version**: 2025-10-29
- **Total Records Analyzed**: 268
- **Analysis Pipeline**: OpenFDA Medical Device Adverse Event Analysis v2.1

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