OPENFDA MEDICAL DEVICE ADVERSE EVENT ANALYSIS

Analysis of FDA Medical Device Adverse Event Reports

BVI Medical

2025-11-19

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1. Executive Summary

This report analyzes **4,262** FDA medical device adverse event reports submitted between **January 01, 2025** and **June 01, 2025** (a period of **5** months). The dataset includes **16** unique manufacturers and **63** unique device brands. The average reporting rate was **710.3** reports per month, with peak reporting of **1208** reports in **April 2025**.

Table 1: Summary statistics of FDA MAUDE reports

Metric	Value
Total Reports	4,262
Date Range	January 01, 2025 to June 01, 2025
Reporting Duration	151 days (5 months)
Unique Manufacturers	16
Unique Device Brands	63
Average Monthly Reports	710.3 reports/month
Maximum Monthly Reports	1208 reports in April 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

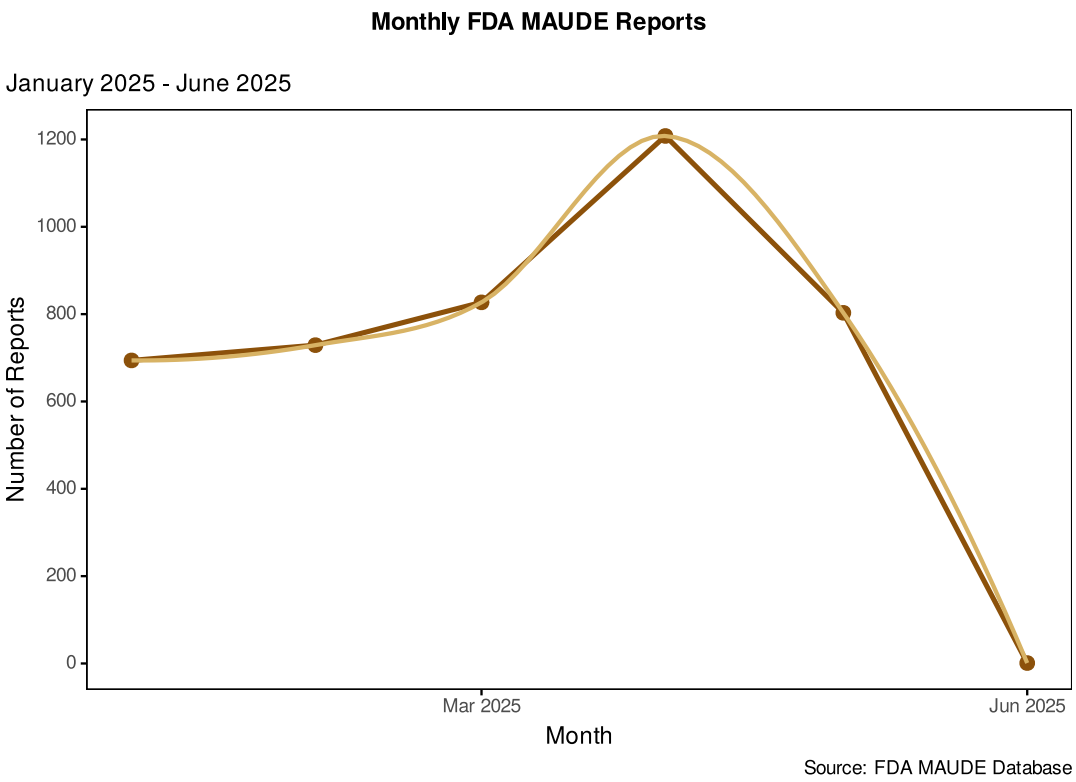

Figure 1: Monthly trend of FDA MAUDE reports

ℹ Trend Observation

The reporting shows variability across months, with notable peaks in **April 2025, March 2025**. The average monthly reporting rate is **710.3** reports, with a standard deviation of **393.4** reports.

3.2. Cumulative Reports Over Time

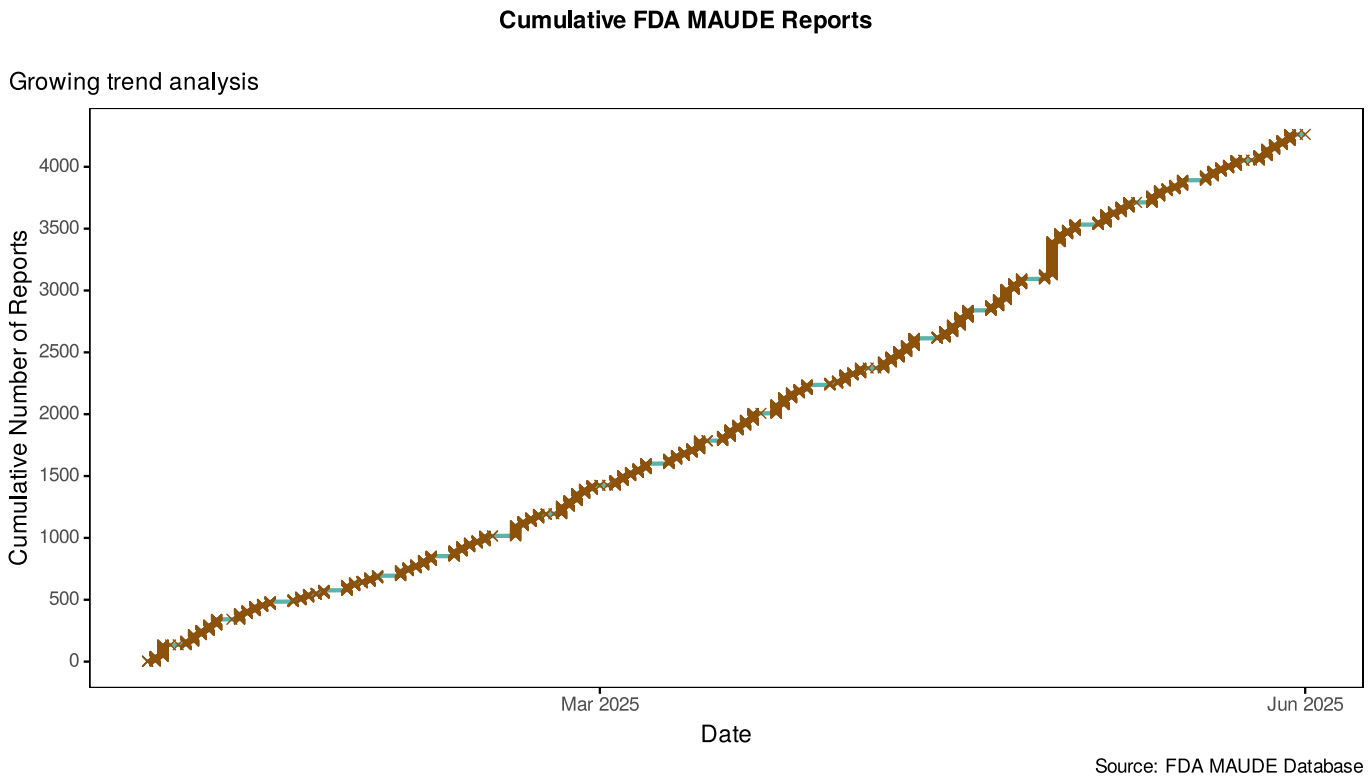

Figure 2: Cumulative FDA MAUDE reports over time

4. Product Problem Analysis

4.1. Top Product Problems

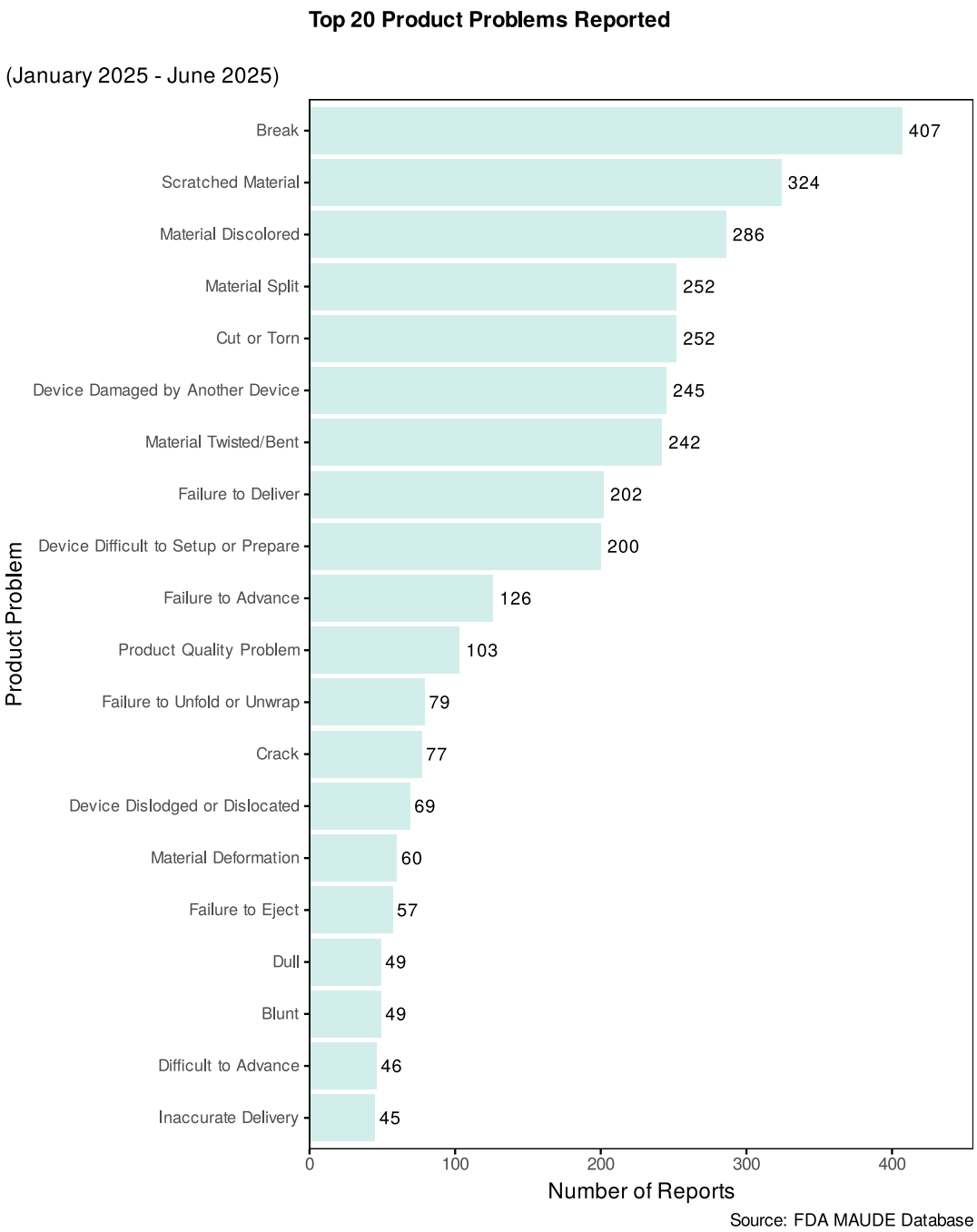

Figure 3: Most frequently reported product problems

⚠ Product Issues

The most frequently reported problems are:

1. **Break** - 407 reports (9.5%)
2. **Scratched Material** - 324 reports (7.6%)
3. **Material Discolored** - 286 reports (6.7%)

These top three issues account for **1017** reports (**23.9%** of all reports).

5. Patient Problem Analysis

5.1. Patient Problems Overview

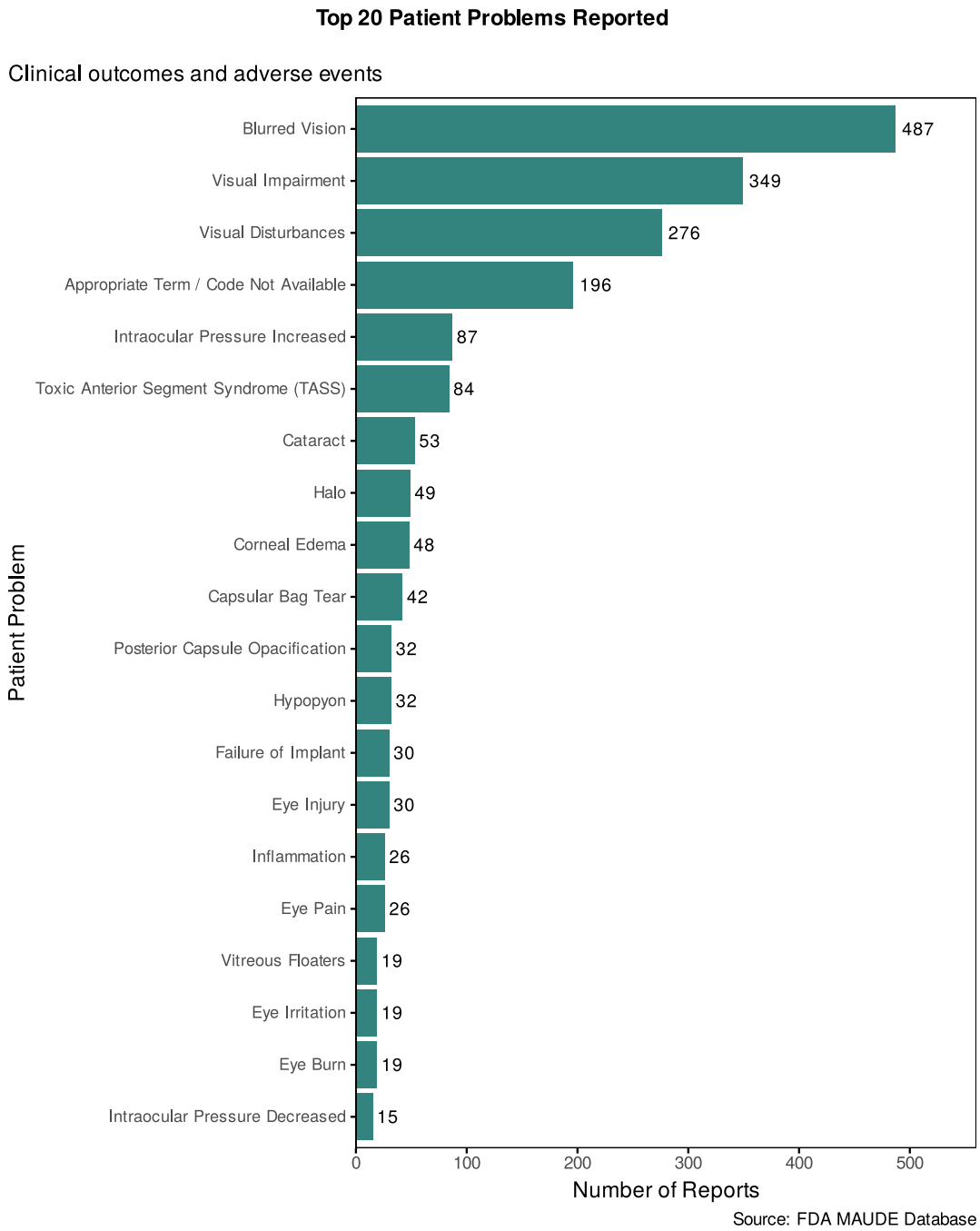

Figure 4: Patient problems reported in FDA MAUDE events

6. Manufacturer Analysis

6.1. Top Manufacturers

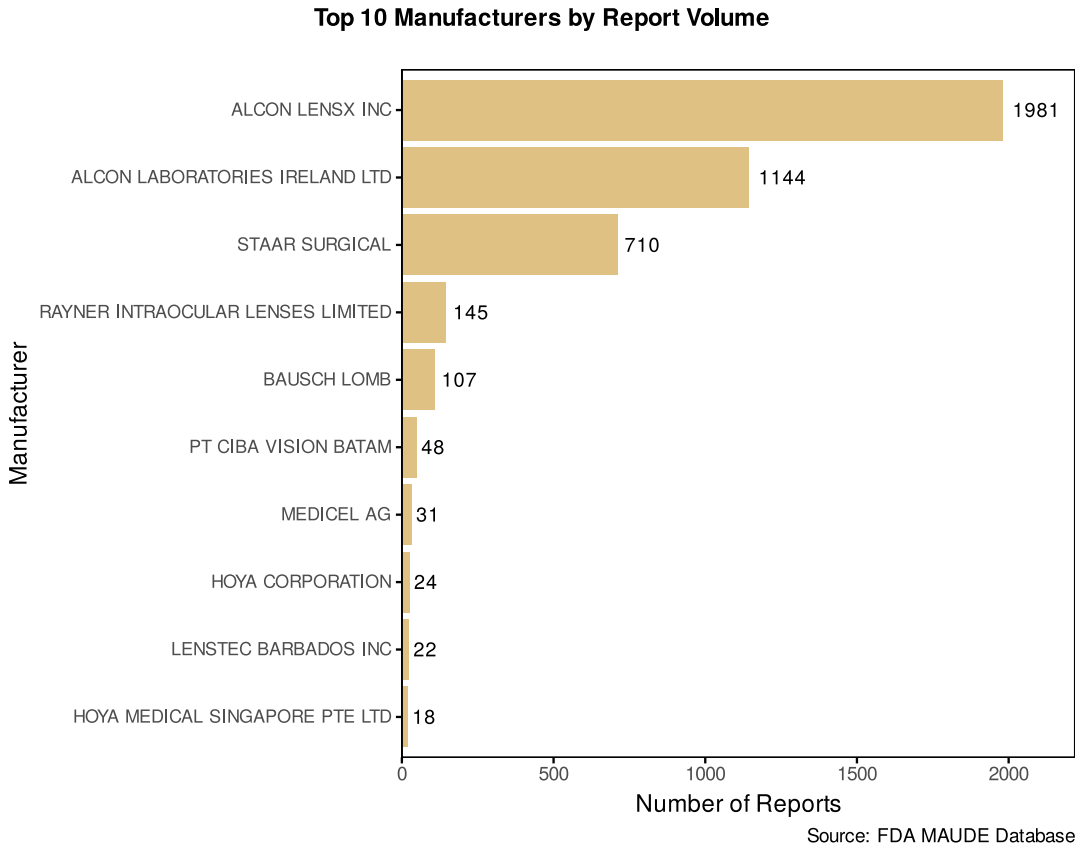

Figure 5: Top 10 manufacturers by report volume

The top manufacturer, **ALCON LENSX INC**, accounts for **1981** reports (**46.5%** of total).

Table 2: Top 5 manufacturers with report statistics

Rank	Manufacturer	Reports	% of Total
1	ALCON LENSX INC	1,981	46.48%
2	ALCON LABORATORIES IRELAND LTD	1,144	26.84%
3	STAAR SURGICAL	710	16.66%
4	RAYNER INTRAOCULAR LENSES LIMITED	145	3.40%
5	BAUSCH LOMB	107	2.51%

7. Device Brand Analysis

7.1. Top Device Brands

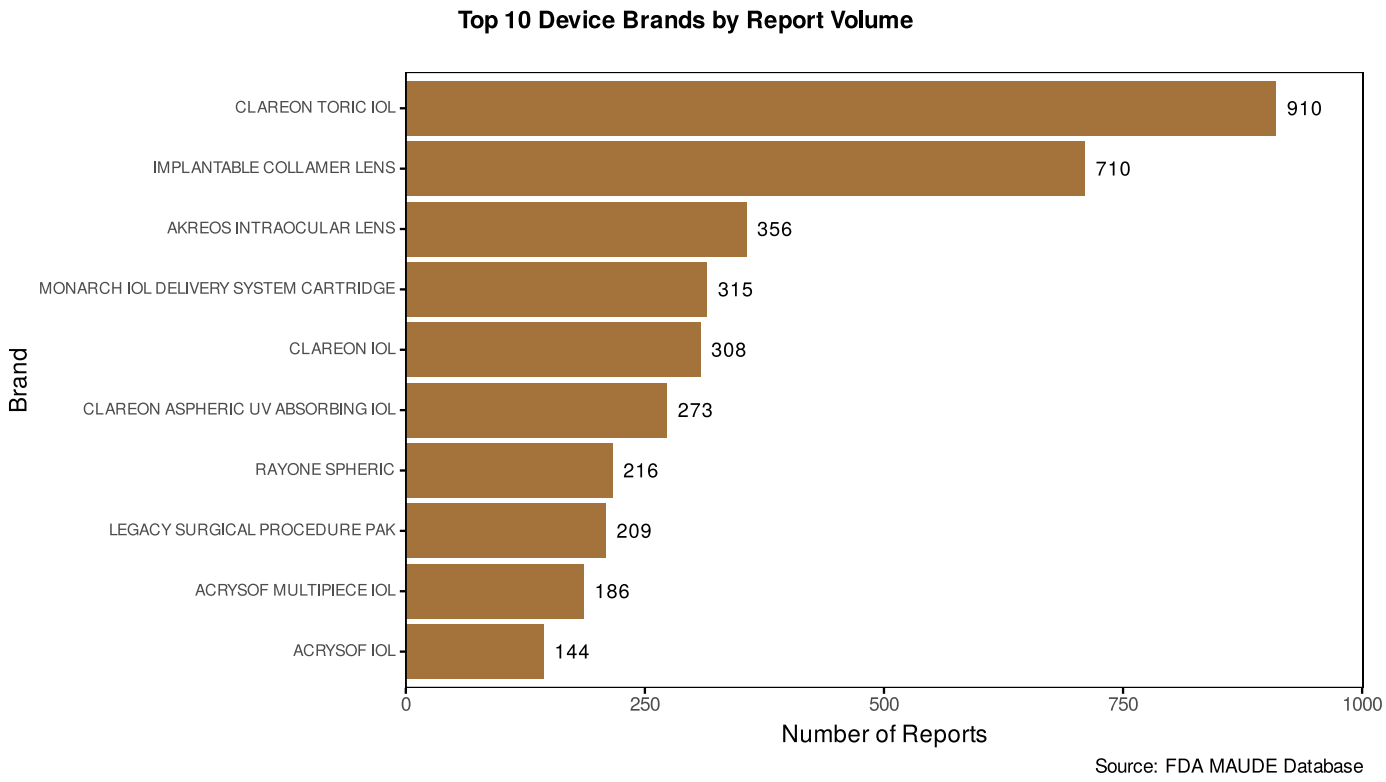

Figure 6: Top 10 device brands by report volume

The top device brand, **CLAREON TORIC IOL**, accounts for **910** reports (**21.4%** of total).

Table 3: Top 5 device brands with report statistics

Rank	Brand	Reports	% of Total
1	CLAREON TORIC IOL	910	21.35%
2	IMPLANTABLE COLLAMER LENS	710	16.66%
3	AKREOS INTRAOCULAR LENS	356	8.35%
4	MONARCH IOL DELIVERY SYSTEM CARTRIDGE	315	7.39%
5	CLAREON IOL	308	7.23%

7.2. Brand Temporal Trends

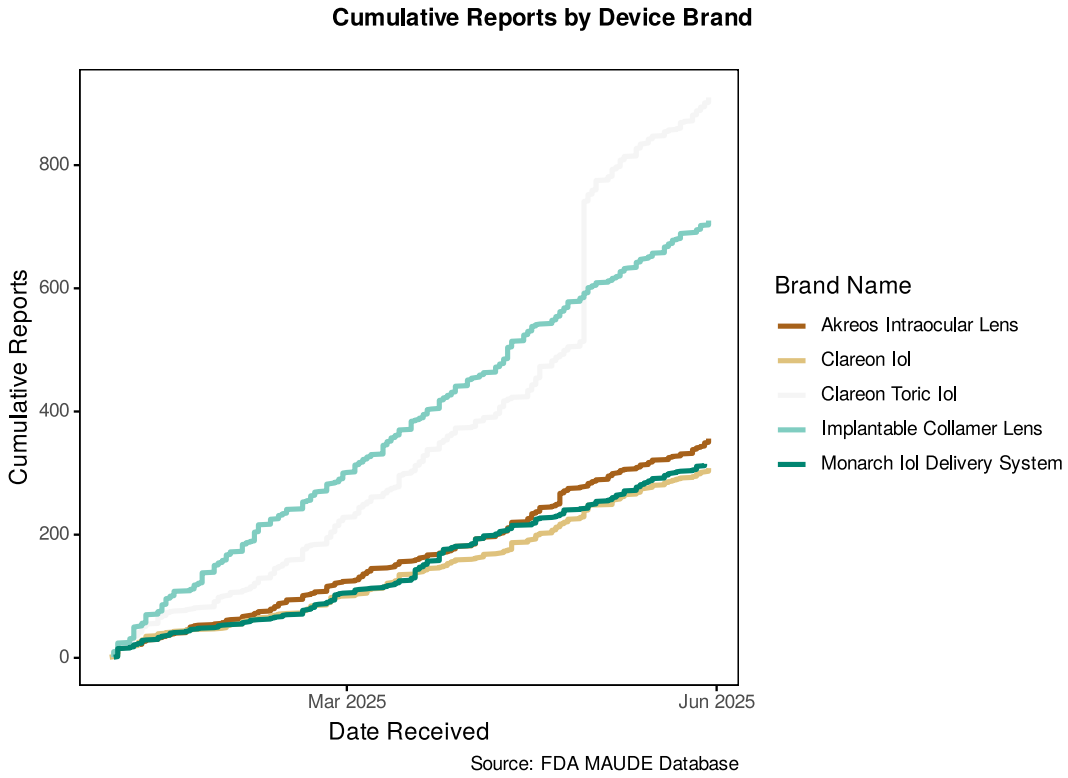

Figure 7: Cumulative adverse event reports by top 5 brands

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 14:41:20
- **Dataset Version**: 2025-06-01
- **Total Records Analyzed**: 4,262
- **Analysis Pipeline**: OpenFDA Medical Device Adverse Event Analysis v2.1

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