OPENFDA MEDICAL DEVICE ADVERSE EVENT ANALYSIS

Analysis of FDA Medical Device Adverse Event Reports

Generated by OpenFDA Analysis Pipeline

2025-11-19

Table of Contents

1. Executive Summary

This report analyzes **119** FDA medical device adverse event reports submitted between **August 18, 2017** and **September 16, 2025** (a period of **96.9** months). The dataset includes **2** unique manufacturers and **9** unique device brands. The average reporting rate was **2.3** reports per month, with peak reporting of **15** reports in **May 2018**.

Table 1: Summary statistics of FDA MAUDE reports

Metric	Value
Total Reports	119
Date Range	August 18, 2017 to September 16, 2025
Reporting Duration	2951 days (96.9 months)
Unique Manufacturers	2
Unique Device Brands	9
Average Monthly Reports	2.3 reports/month
Maximum Monthly Reports	15 reports in May 2018

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

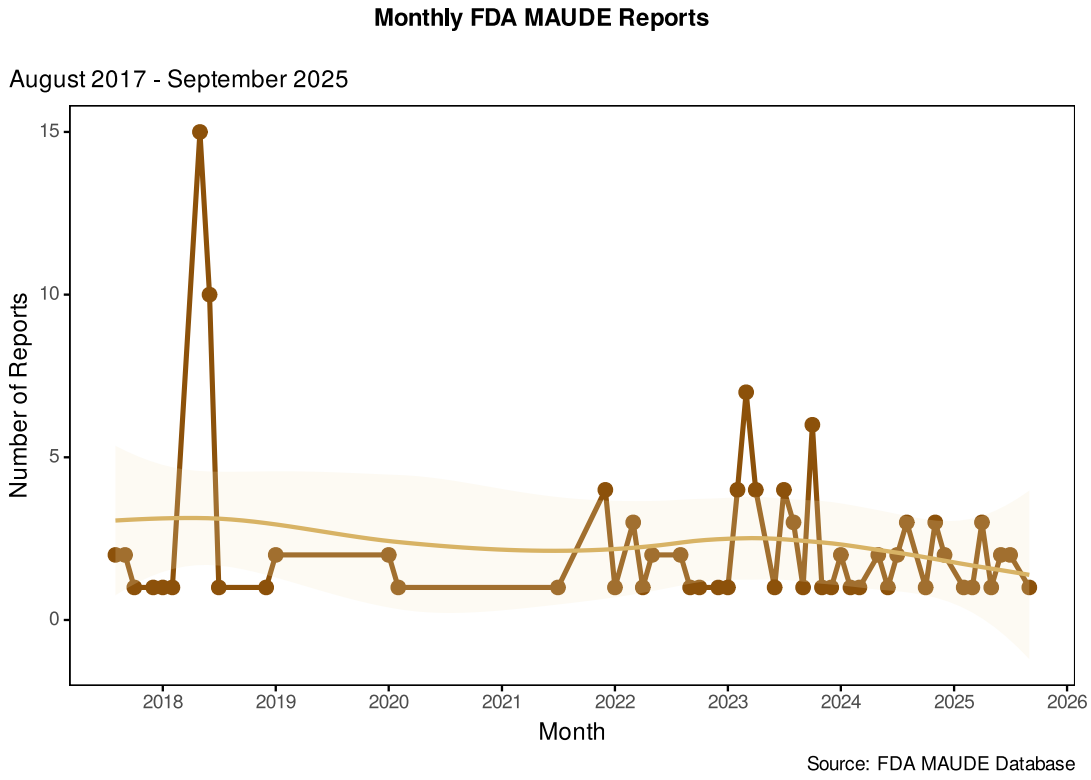

Figure 1: Monthly trend of FDA MAUDE reports

i Trend Observation

The reporting shows variability across months, with notable peaks in **May 2018**, **June 2018**, **March 2023**, **October 2023**, **December 2021**, **February 2023**, **April 2023**, **July 2023**, **March 2022**, **August 2023**, **August 2024**, **November 2024**, **April 2025**. The average monthly reporting rate is **2.3** reports, with a standard deviation of **2.5** reports.

3.2. Cumulative Reports Over Time

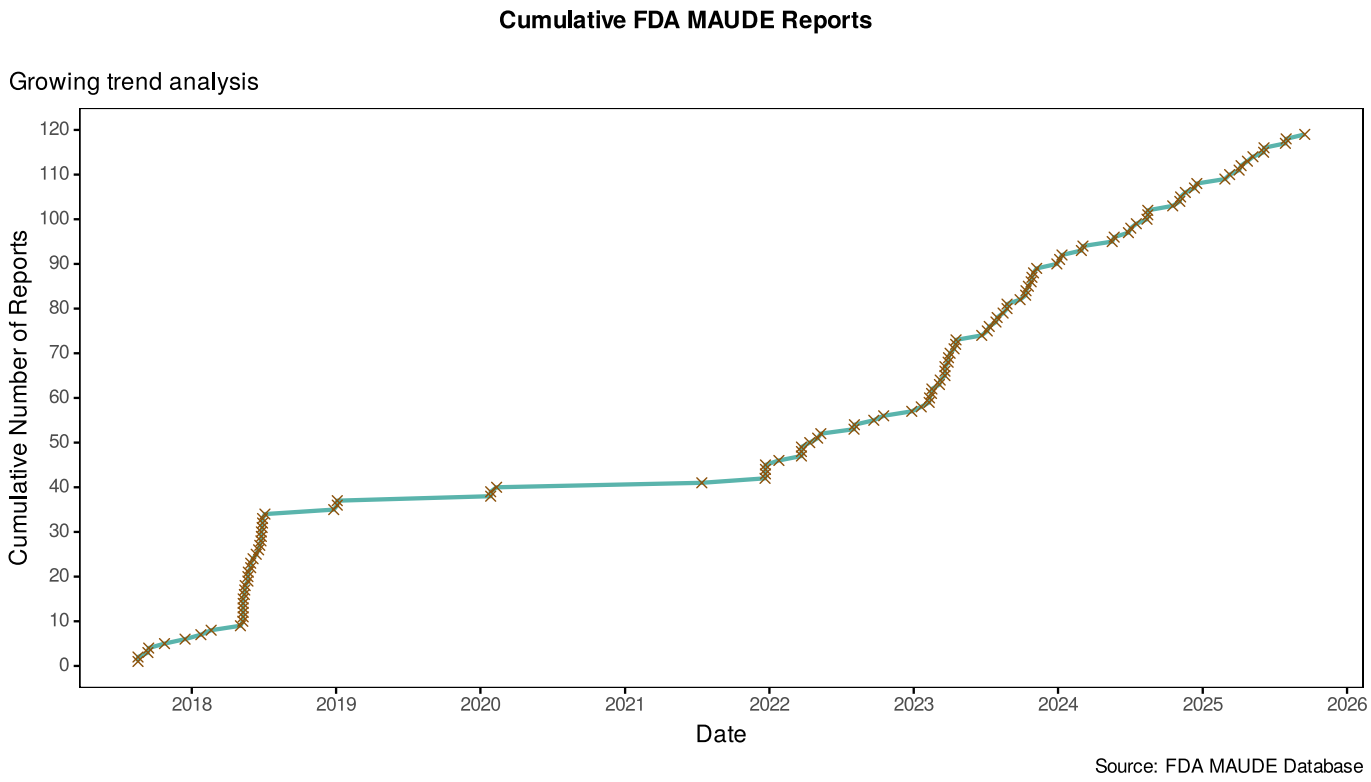

Figure 2: Cumulative FDA MAUDE reports over time

4. Product Problem Analysis

4.1. Top Product Problems

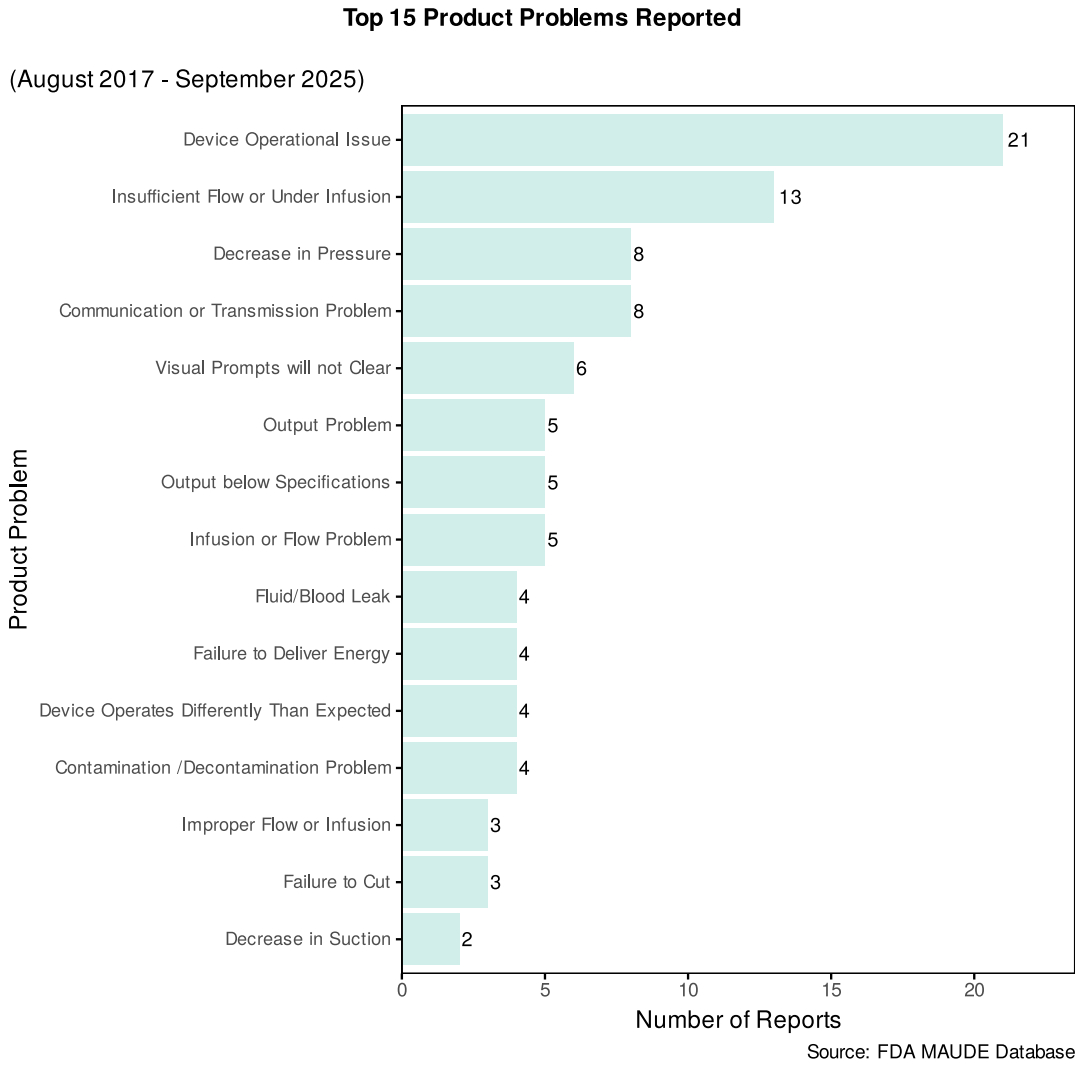

Figure 3: Most frequently reported product problems

⚠ Product Issues

The most frequently reported problems are:

1. **Device Operational Issue** - 21 reports (17.6%)
2. **Insufficient Flow or Under Infusion** - 13 reports (10.9%)
3. **Communication or Transmission Problem** - 8 reports (6.7%)

These top three issues account for **42** reports (**35.3%** of all reports).

5. Patient Problem Analysis

5.1. Patient Problems Overview

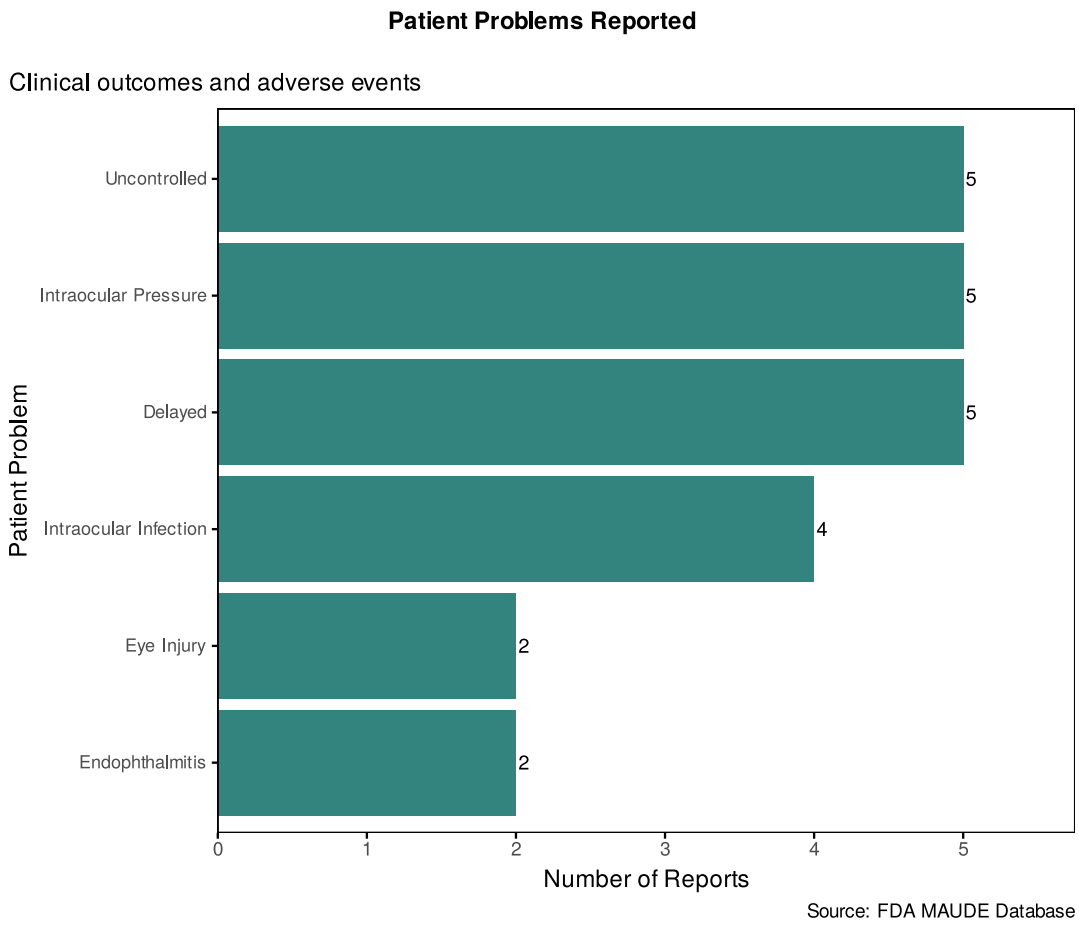

Figure 4: Patient problems reported in FDA MAUDE events

6. Manufacturer Analysis

6.1. Top Manufacturers

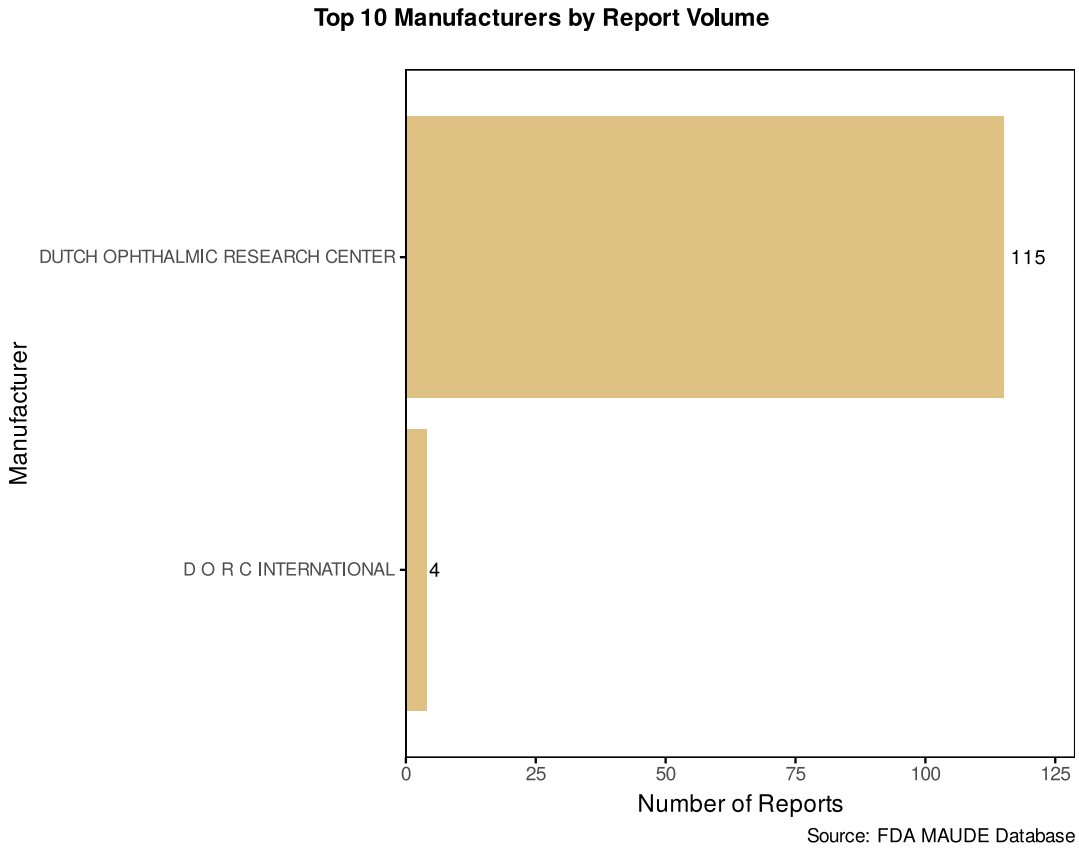

Figure 5: Top 10 manufacturers by report volume

The top manufacturer, **DUTCH OPHTHALMIC RESEARCH CENTER**, accounts for **115** reports (**96.6%** of total).

Table 2: Top 5 manufacturers with report statistics

Rank	Manufacturer	Reports	% of Total
1	DUTCH OPHTHALMIC RESEARCH CENTER	115	96.64%
2	D O R C INTERNATIONAL	4	3.36%

7. Device Brand Analysis

7.1. Top Device Brands

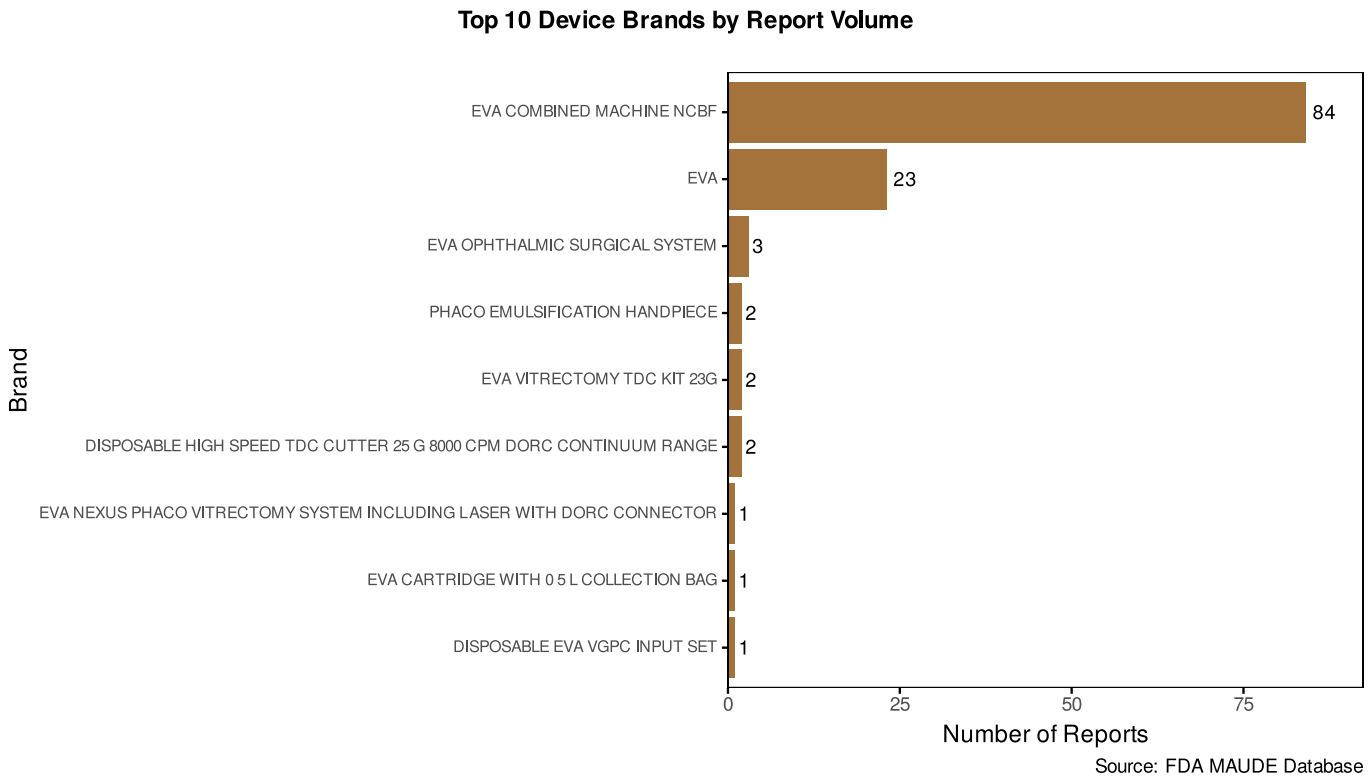

Figure 6: Top 10 device brands by report volume

The top device brand, **EVA COMBINED MACHINE NCBF**, accounts for **84** reports (**70.6%** of total).

Table 3: Top 5 device brands with report statistics

Rank	Brand	Reports	% of Total
1	EVA COMBINED MACHINE NCBF	84	70.59%
2	EVA	23	19.33%
3	EVA OPHTHALMIC SURGICAL SYSTEM	3	2.52%
4	DISPOSABLE HIGH SPEED TDC CUTTER 25 G 8000 CPM DORC CONTINUUM RANGE	2	1.68%
5	EVA VITRECTOMY TDC KIT 23G	2	1.68%

7.2. Brand Temporal Trends

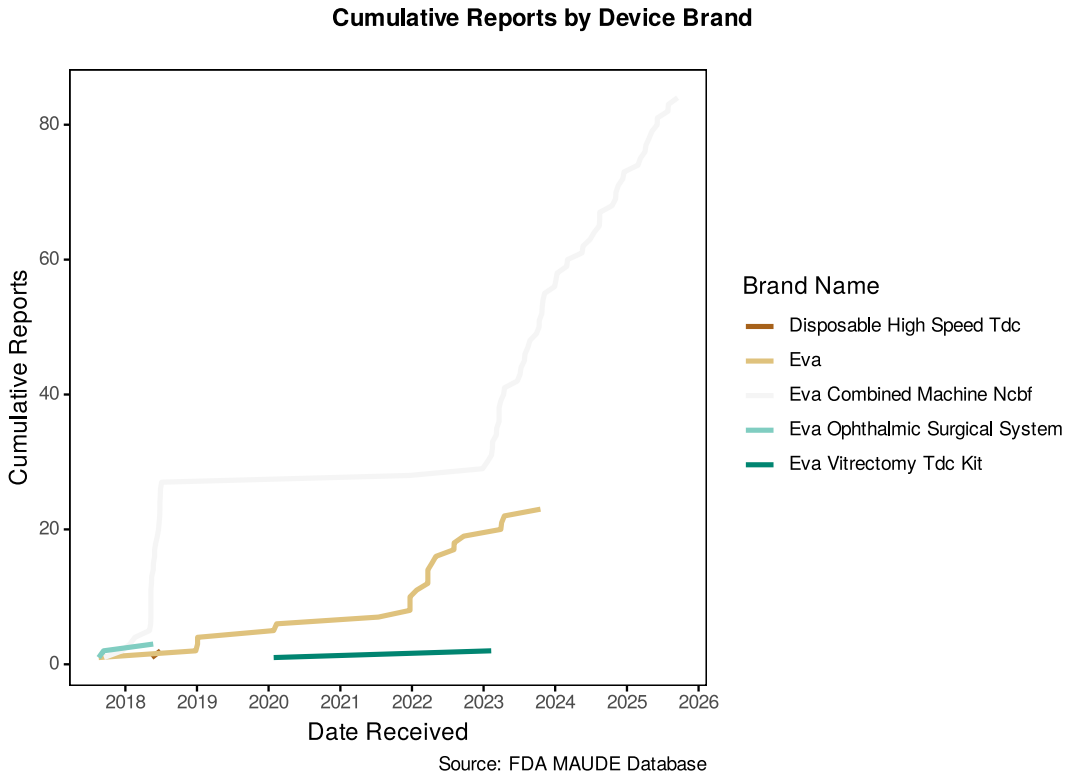

Figure 7: Cumulative adverse event reports by top 5 brands

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 14:04:42
- **Dataset Version**: 2025-09-16
- **Total Records Analyzed**: 119
- **Analysis Pipeline**: OpenFDA Medical Device Adverse Event Analysis v2.1

List of Figures

List of Tables