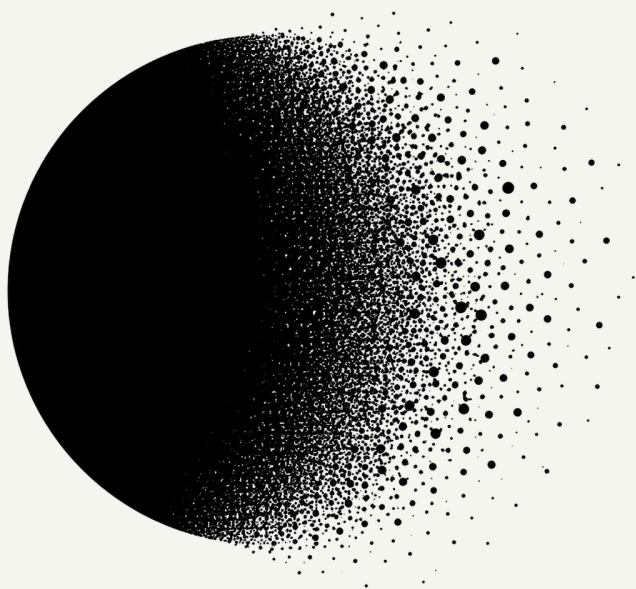




GUIDE 02 FDA DATA

Searching MAUDE with purpose

How to build a reproducible search of FDA device data, read the reports critically, and respect the limits of the data.



ABOUT

MAUDE is the first place most people look after a device problem. It is also where many searches go wrong. A count of reports is not a rate, and a report is not a finding.

This guide shows how to build a search that another person can repeat, how to read the reports behind the numbers, and how to connect them with recall and clearance records. It also explains what the data cannot tell you.

FOR

Legal counsel who evaluate a claim or prepare discovery.
Manufacturers — complaint, quality, and regulatory teams.
Hospitals — risk managers and clinical engineering checking a device’s history.

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This guide is general technical information. It is not legal advice. FDA databases change; confirm the current search options and data coverage on each FDA page before you rely on them.

01

What MAUDE is, and what it is not

MAUDE, the Manufacturer and User Facility Device Experience database, holds the medical device reports (MDRs) that FDA receives. Manufacturers and importers must submit reports of certain events. Device user facilities, such as hospitals, must report deaths and serious injuries. Health professionals, patients, and others may submit voluntary reports.

Each report describes a suspected link between a device and an event: a death, a serious injury, or a malfunction. The report records what the reporter believed at the time. FDA does not verify it.

COVERAGE

The online search covers reports from about the last ten years and returns up to 500 records per search. Older reports and complete data sets are in FDA's downloadable MDR data files. The openFDA device adverse event interface gives programmatic access.

VALUE

Used with care, MAUDE shows how a device has failed in the field, how the manufacturer described its investigation, and how failure descriptions changed over time.

FDA ON MAUDE

"The incidence, prevalence, or cause of an event cannot be determined from this reporting system alone."

02

Define the question first

A useful search starts from a written question. For example: have other users reported the same failure mode, in the same model, in the years before this event? Write the question down before you search. It decides every filter that follows.

01

Identify the device exactly

Record the brand name, model and catalog numbers, manufacturer, and the device identifier from the UDI. AccessGUDID confirms the identifier and its device description. FDA's Product Classification database gives the three-letter product code.

Note other names under which the device was sold, related models, and earlier or later versions. Each can hold relevant reports.

02

Choose the dates, and say which dates

A report carries several dates, among them the date of the event and the date FDA received the report. Decide which date defines your window and state it with the results.

Reports often arrive weeks or months after the event. A window that ends close to today will undercount recent events.

FIGURE

The search funnel



FIG 01 Narrow the search in recorded steps and write down the count at each level. Another reader should be able to rerun the search and reach the same records, allowing for reports added since.

03

Search in layers

Start broad and narrow in recorded steps: product code, then date window, then brand and manufacturer. Try several spellings of each name. Companies merge, rename, and report under different legal entities.

Do not filter on device problem codes alone. The reporter chooses the codes, and the code lists have changed over time. Use them to sort the results, not to exclude reports.

04

Record the search

Keep a search log as you work. Save every export unchanged, and work on copies. A short log is enough:

STEP	FILTER APPLIED	COUNT	EXPORT FILE
1	Product code [ABC], all dates	n1	L1.csv
2	+ event date, 5-year window	n2	L2.csv
3	+ brand "Device X", 3 spellings	n3	L3.csv
4	Narratives read; criteria applied	n4	L4.xlsx

Example structure only. Record the date each search was run and the database used.

NOTE

The MAUDE web search returns at most 500 records. If a step reaches that limit, split it into shorter date ranges or work from the MDR data files, and record how the parts were combined.

03

Read the reports, not the counts

A count of reports is a starting point. The information that matters is in the text of each report.

EVENT TYPE	Death, injury, malfunction, or other, as classified by the reporter.
NARRATIVES	The event description, and a separate manufacturer narrative that may give the results of its investigation.
CODES	Device problem and patient problem codes chosen by the reporter.
REDACTIONS	Text marked (b)(4) is withheld as confidential commercial information; (b)(6) protects personal privacy.

05

Read every narrative

Open each report in the final set. Look for the same model, the same failure mode, and the same conditions of use. Note whether the device was returned and evaluated, and what the evaluation found.

06

Classify with written criteria

Before reading, write the rules for what counts as relevant. Apply them in the same way to every report, and record the reason for each decision. Have a second reviewer check a sample.

04

Know the limits of the data

These limits do not make MAUDE useless. They decide what a careful analysis may claim. State them next to the numbers: a count presented without them will be read as a rate.

01

Under-reporting

Many events are never reported. The count is a minimum, not a measure.

02

Duplicates

One event can produce reports from the facility, the manufacturer, and a voluntary reporter, plus supplemental reports.

03

Summary reports

Under FDA's voluntary malfunction summary reporting program, one record can stand for many similar malfunctions.

04

Stimulated reporting

Publicity, recalls, and litigation can increase reporting with no change in the device.

05

No denominator

MAUDE does not record how many devices are in use, so counts are not rates.

06

Unverified content

A narrative records what the reporter believed. It is not a finding.

05

Connect recalls and clearances

MAUDE is one of several public FDA databases. Read together, they give the regulatory history of a device.

RECALLS

The Medical Device Recalls database lists recalls by product and firm, with the reason and the recall class. Class I is the most serious: use of the product may cause serious adverse health consequences or death.

510(K)

The 510(k) database gives the clearance number, decision date, and product code. The summary often names the predicate device and the testing submitted. Higher-risk devices go through PMA or De Novo, which have their own databases.

CLASS

The Product Classification database links a product code to its regulation number and device class.

TPLC

The Total Product Life Cycle report brings premarket, adverse event, and recall information together for one product code.

NOTE

A recall, a clearance, or a group of reports does not establish the cause of a particular incident. Each answers a different question. The cause comes from the device, its data, and testing.

CHECKLIST

Search worksheet

- ☐ Question written down before searching
- ☐ Device identified: brand, model, manufacturer, UDI
- ☐ Product code or codes confirmed
- ☐ Date field and window chosen and stated
- ☐ Name variants and related models listed
- ☐ Count recorded at every step; exports saved unchanged
- ☐ Relevance criteria written before reading
- ☐ Every narrative in the final set read
- ☐ Duplicates and summary reports identified
- ☐ Recalls, clearances, and limits reported with results

SOURCES

FDA — MAUDE database search

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm>

FDA — MDR data files

<https://www.fda.gov/medical-devices/medical-device-reporting-mdr-how-report-medical-device-problems/mdr-data-files>

openFDA — Device adverse events

<https://open.fda.gov/apis/device/event/>

FDA — Medical Device Recalls database

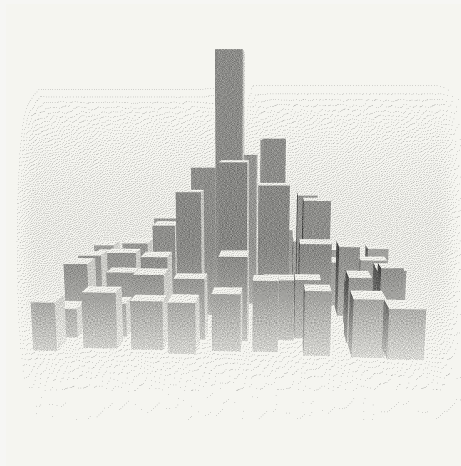
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm>

FDA — 510(k) Premarket Notification database

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm>

NLM — AccessGUDID

<https://accessgudid.nlm.nih.gov/>



SERVICES

FDA data, read by engineers

We place an incident in context with adverse-event reports, recalls, and regulatory history, and we connect what the records say with how the device actually works.

01

Reproducible searches

A documented search log and unchanged exports, ready to support a report or an expert disclosure.

02

Report-by-report review

Each narrative read by an engineer and classified against written criteria.

03

Engineering context

Reported failure modes linked to the device design, its test evidence, and its records.

CONTACT

Tell us about the device.

Send the device name, the question you need answered, and any deadlines. We will tell you what the FDA data can and cannot show, and recommend the next steps.

EMAIL info@alphadevices.io

WEB alphadevices.io

GUIDES

- 01 A device failed. What happens next?
- 02 **Searching MAUDE with purpose**
- 03 Understanding waterfall design

Alpha Devices

2101 Brandywine Street, Suite 200
Philadelphia, PA 19130

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