Medical Device Recall Monitoring: Illustrative Evidence Brief

ILLUSTRATIVE SPECIALIST EVIDENCE BRIEF | PUBLIC-SOURCE AND SERVICE METHODOLOGY

No completed client matter is represented. This document demonstrates questions, evidence requirements, limitations and possible deliverables. It contains no verified findings about a named buyer or company. A matter, source access, fixed fee and timing require separate written acceptance.

Commissioned decision

This specialist review focuses on **Medical Device Recall Monitoring**, within **Pharmaceuticals, Biotechnology & Medical Device Intelligence**. The decision owner asks: **What is the authoritative product, trial and regulatory-record status?** The specific fact being tested, relevant entity, territory and historical period must be defined before any casework.

Narrow first commission

Investigate one named subject, one agreed current-versus-historical claim, the most relevant `product manufacturer registration` and one independent cross-check. Stop if original records are unavailable or the decision cannot be resolved in the agreed scope.

Original-record plan

- Source the exact original `product manufacturer registration` and capture jurisdiction, publisher and date.
- Verify identity against `FDA device database` and document whether it is independent.
- Test `recall absent due to search limitation` as a rival explanation.
- Check the alternative `trial not approval` rather than treating an unreturned search result as exculpatory.
- Ask whether `device name mismatch` would require the decision owner to commission a qualified specialist.

Illustrative two-page PDF composition

Page 1: Case-neutral purpose, exact research questions, allowed source universe and decision relevance; do not name a supposed real client.

Page 2: Source-to-question matrix with no fabricated findings, a material contradiction register, a precise request for the missing original records and reliance boundaries.

Specific deliverable tables: manufacturer evidence map, regulated product state brief, trial-source crosswalk.

Example report table (empty until an authorised case)

Evidence question; Proposed source; What must be verified; Result

Which entity/asset is named?; product manufacturer registration; Exact identifiers and record period; Not investigated in this specimen

Does the claim survive a contrary source?; FDA device database; Independence, timing and scope; Not investigated in this specimen

What would change the answer?; ClinicalTrials.gov; recall absent due to search limitation; Not investigated in this specimen

Applicable source portals

Ref; Primary source / comparator; Link; Evidence limitation and status

FDA-DEVICE; U.S. FDA: openFDA device recall API; https://open.fda.gov/apis/device/recall/how-to-use-the-endpoint/; WEB CHECKED 2026-10-12. Database refresh and product name ambiguity require original FDA reconciliation

FTC-ADS; U.S. FTC: Advertising substantiation standards FAQ; https://www.ftc.gov/business-guidance/resources/advertising-faqs-guide-small-business; WEB CHECKED 2026-10-12. US advertising context; scientific/health claims may require specialised testing not performed by Aperture

S16; U.S. FDA open data for devices; https://open.fda.gov/apis/device/; REGISTER STARTING POINT; NOT NEWLY RECHECKED. Source candidate; subject relevance, date and access must be verified case-by-case.

Buyer action and exclusions

- Reader: Life-science investors, device manufacturers, counsel and procurement.
- Commercial trigger to check: FDA communication, study update, device recall or partner review.
- Send the decision question and identifiers through the existing written-enquiry route; do not send restricted records by insecure email.
- **Professional boundary:** No medical advice, efficacy certification or approval determination.
- Do not imply the claimed facts are proven, that this is a completed sample case, or that named competitors have endorsed Aperture.

Release quality controls

- Confirm the appointing client, exact research question, relevant location, decision date, conflicts, privacy, sanctions and licensing.
- Check original source identity, authority, issue date, effective date, retrieval timestamp, version and lawful access.
- Reproduce important calculations and compare at least one plausible contrary explanation.
- Keep allegations, regulatory findings, historical claims and unresolved matches distinct.
- Mark each proposed finding supported, partially supported, contradicted, unresolved or outside mandate; include missing-source requests.
- Confirm that illustrations do not imply a real engagement, completed investigation, certified outcome or affiliation with named comparators.
- Obtain final human sign-off on accuracy, legal boundaries, confidentiality, claims and publication version before release.

Professional boundaries: Independent research support only. No legal, tax, investment, audit, valuation, brokerage, investigation requiring a specific professional licence or regulated opinion is implied. No confidential material should be sent before instructions.