PUBLIC RECORDS / WORKED EXAMPLE

PENTAX OS-H5: reading a recall

Ten decisions from the public record | Part 4

Prepared by Dossier Editorial | November 4, 2026

EVIDENCE SOURCES	EVIDENCE CHECKED	PUBLISHER INSTITUTIONS
2	2026-11-04	1

SECTIONS	READER QUESTIONS	REVIEW SCOPE
7	3	Public records

EVIDENCE CHECKED	2026-11-04
EDITION	1 | Public-source research
ARTICLE	dossierplus.ai/blog/pentax-os-h5-recall-vendor-diligence

IMPORTANT USE NOTE

Retrospective public-source walkthrough, first published November 4, 2026. Prepared with AI assistance. This is an educational worked example, not a client investigation, legal opinion, or record of a live Dossier research run. No human legal review is claimed.

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PART 01

The decision in brief

A recall can involve a correction rather than removal from use or sale. FDA's October 28, 2026 OS-H5 entry describes an instructions-for-use update and remained Open, Classified when checked. A supplier review should match the affected device and obtain the current manufacturer notice and implementation evidence; the listing alone does not prove completion.

Publication date: November 4, 2026. Historical event dates are identified separately. This PDF and the article use the same structured source selection and findings.

PART 02

Executive summary

FDA recall Z-0310-2027, event 99782, identifies the PENTAX Medical OS-H5 water bottle assembly and Pentax of America Inc. The record covers all serial numbers under four listed UDI-DIs. It reports 2,972 units in commerce, a quantity measure rather than a patient-injury or correction-completion count. **[S01]**

The stated action concerns updated warnings and instructions for use. FDA's general guidance explains that recalls can be corrections or removals. The review supports an open recall and an identified action; it does not establish that a particular facility completed it. **[S01] [S02]**

PART 03

Define an inventory question, not a clinical conclusion

The audience here is a supplier or inventory reviewer. The question is whether a local device matches an affected product and whether the responsible team has evidence of the required response. This article does not advise how to operate a medical device or determine patient suitability. Qualified clinical and device-safety personnel should use the current manufacturer instructions.

Match the model and UDI-DI to the actual inventory record. Keep the assembly distinct from any related endoscope named in the notice. A matching manufacturer name alone is not a product match; an approximate model string is an unresolved lead.

PART 04

Separate the notice, initiation, and posting dates

DATE	RECORDED EVENT	INTERPRETATION
September 2, 2026	Field safety notice date	Date of the notice described in FDA's action field. [S01]
September 9, 2026	Firm initiation date	The correction began before public posting. [S01]
October 28, 2026	FDA posting date	The development in this retrospective window. [S01]

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DATE	RECORDED EVENT	INTERPRETATION
November 4, 2026	This review checks Open, Classified status	A dated observation; later status may change. [S01]

PART 05

The answer and its limits

Outcome: product scope supported in the FDA record. Keep each UDI-DI in a structured identity field when doing a real inventory match. This public example does not contain a customer's inventory, so it cannot say whether that customer has an affected unit.

Outcome: corrective action described, completion unresolved. A notice sent to a consignee, a staff acknowledgment, an updated instructions set, and a completed local action are different pieces of evidence. Preserve the actual document and the responsible team's dated implementation record.

Outcome: cause not resolved in the reviewed database entry. FDA lists the cause as unknown or undetermined by the firm. Do not invent a manufacturing defect or translate the existence of a recall into a finding of harm. **[S01]**

PART 06

The recall review decision tree

1. DOES THE INVENTORY MODEL AND IDENTIFIER MATCH THE AFFECTED SCOPE?

- If established: Route the exact notice to the responsible device-safety owner.
- If unresolved: Keep the identity question open and obtain an authoritative inventory match.

2. IS THE CURRENT REQUIRED ACTION AVAILABLE FROM THE MANUFACTURER?

- If established: Record that action and its version without paraphrasing clinical instructions into a new protocol.
- If unresolved: Request the current notice; a headline is insufficient.

3. IS COMPLETION DOCUMENTED FOR THE MATCHED INVENTORY?

- If established: Retain the dated local evidence and separately recheck the agency status.
- If unresolved: Report implementation as unresolved; do not mark a notice as completed merely because it was received.

PART 07

Document the review in Dossier

Create one matter keyed to recall number and product model. Save the FDA entry with its retrieval time and the manufacturer notice when obtained. Add questions for identity match, required action, local implementation, and agency status. Attach source anchors to each answer independently.

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Keep the public posting date separate from the firm's initiation date. Record the product count with its original field label. In a client review, place private inventory and staff acknowledgments only in the authorized private workspace, never in public blog content. This article used no such records and did not execute a live platform investigation.

PART 08

What would close the evidence gap?

A matched inventory record, current original manufacturer instructions, a dated implementation record from the responsible team, and a fresh agency status check would materially improve the packet. Each answers a different question. Agency termination and completion at one facility should not be treated as interchangeable findings.

PART 09

Questions readers ask

DOES THE 2,972 FIGURE MEAN INJURIES?

No. The FDA field is quantity in commerce. It does not report that many injuries or completed corrections. **[S01]**

WAS THE RECALL INITIATED ON OCTOBER 28?

No. That is the posting date; the firm initiation date is September 9. **[S01]**

DOES EVERY RECALL REQUIRE RETURNING THE DEVICE?

FDA explains that some recalls are corrections rather than removals. Follow the exact current action for the matched product. **[S02]**

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PART 10

Linked source register

Titles with a recorded URL link to that source. Entries without a URL identify retained material but do not open an original file. For any court or business record being used in litigation, obtain a certified copy directly from the clerk or filing authority and preserve the retrieval date.

S01 **FDA Class 2 device recall: PENTAX Medical water bottle assembly**
Recall database entry. Anchor: Recall Z-0310-2027; product, code information, dates, action, quantity, status. Public status checked November 4. No facility inventory or implementation record reviewed. · retrieved 2026-11-04

S02 **What is a medical device recall?**
Agency guidance. Anchor: Correction and removal definitions; recall process. General explanation, not a replacement for the device-specific notice. · retrieved 2026-11-04

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