

Is this complaint **reportable**, and by when?

PMS / REPORTABILITY AID

FDA 21 CFR PART 803

EU MDR ARTICLE 87

WORK DOWN. FIRST MATCH WINS.

FDA / UNITED STATES

01	Death the device may have caused or contributed to Form 3500A via eMDR. 803.50(a)(1)	30 CAL
02	Serious injury, as defined below Form 3500A via eMDR. 803.50(a)(1)	30 CAL
03	Malfunction likely to cause death or serious injury if it recurred Nobody need be harmed. Quarterly summary instead if the product code is VMSR-eligible. 803.50(a)(2)	30 CAL
04	None of the above Not reportable. Document the rationale in the complaint record.	NONE

OVERRIDE: 5 WORKING DAYS
Remedial action needed to prevent an unreasonable risk of substantial harm to public health, or FDA has made a written request. 803.53

EU MDR / EUROPEAN UNION

01	Serious public health threat Immediately, and no later than 2 days. Escalate now. Art. 87(5)	2 DAYS
02	Death, or unanticipated serious deterioration in health Report as soon as causality is established or suspected. Art. 87(4)	10 DAYS
03	Any other serious incident The period should reflect severity, so 15 days is a limit and not a target. Art. 87(3)	15 DAYS
04	Expected side effect meeting all three exemption conditions Article 88 trend reporting, with an explanatory statement.	TREND
05	Not a serious incident No individual report. Confirm it is captured in trend analysis.	NONE

DEFINITIONS YOU WILL LOOK UP

Serious injury: any one limb

Life-threatening · permanent impairment of a body function · permanent damage to a body structure · necessitates medical or surgical intervention to preclude permanent impairment or damage. "Permanent" means irreversible, excluding trivial. 803.3

Became aware: two different thresholds

30-day and FDA-requested 5-day reports: ANY employee. Remedial-action 5-day report: an employee with management or supervisory responsibility over regulatory, scientific or technical staff, or whose duties relate to collecting and reporting adverse events. 803.3

Article 87 exemption: all three must hold

Clearly documented in the product information · quantified in the technical documentation · subject to Article 88 trend reporting. Satisfying two of the three is not an exemption.

WHERE PEOPLE GET CAUGHT

- The units differ. 30 days is calendar, 5 days is working.
- "Reasonably suggests" is a lower bar than established causality. FDA does not wait for your conclusion.
- Reporting is not an admission that the device caused the event. 803.16
- VMSR eligibility is per product code and FDA revises it. Check the Product Classification Database.
- EU and FDA can reach different answers on the same facts. That is expected, and not a mistake.
- An investigator reviews the non-reportable determinations first, so the rationale has to stand on its own.

STOP AND ESCALATE: THREE PLACES THIS AID WILL NOT DECIDE FOR YOU

S1 Outcome unknown, or still under investigation The clock is already running from awareness, and a pending investigation does not pause it. Set a review date inside the shortest applicable deadline.	S2 Recurrence consequence cannot be assessed Whether a recurrence would likely cause death or serious injury is a risk judgment. Make it with the risk file open, not from the complaint record alone.	S3 Causality contested internally The FDA threshold is deliberately low, so a decision not to report over internal disagreement needs documented sign-off above the handler.
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Available at any point: if this looks like it may require a field safety corrective action, or a correction or removal reportable under 21 CFR 806, stop and notify now.

DETERMINATION RECORD, TO COPY INTO THE COMPLAINT FILE

COMPLAINT _____	ORGANIZATIONAL AWARENESS (not receipt) _____
FDA determination _____	due _____ basis _____
EU determination _____	due _____ basis _____
RATIONALE _____	
ASSESSED BY _____	DATE _____ REG. TEXT AS OF 4 OCT 2026

Demonstration piece built from publicly available regulation, current as of 4 October 2026. Not regulatory advice. Your organization's procedures and your notified body's requirements govern. Scope: legal manufacturer obligations for finished medical devices. Not combination products, IVDs, importers or user facilities. Does not cover 21 CFR 806 corrections and removals, or FSCA execution.