

AI-ASSISTED EVIDENCE REVIEW

Non-Surgical Skin-Tightening Devices

A branded-device comparison for UK aesthetic clinic owners

Five platforms examined

Ultherapy / Ultherapy PRIME | Thermage FLX | Sofwave | Morpheus8 | Potenza

Research date: 21 September 2026

Prepared as an example of buyer-side AI research — not as a device recommendation.

Important

This is a targeted AI-assisted evidence review, not a protocol-registered systematic review, medical advice, or regulatory advice. Evidence strength is described qualitatively and deliberately avoids declaring a universal “winner”. Before purchase, verify the exact model, software, handpiece/tip, indication, UK conformity status, training requirements, post-market safety data and commercial terms.

1. Executive summary

The main finding is not that one machine is universally superior. It is that the amount and type of evidence supporting these five highly marketed platforms differs materially — and much of that difference disappears if a buyer only asks whether the underlying technology is “clinically proven”.

Platform	Technology	Device-specific evidence	US FDA wording	Key due-diligence issue
Ultherapy / PRIME	MFU-V	Relatively strong for legacy Ulthera; PRIME-specific evidence smaller	Explicit eyebrow and lax submental/neck lifting	Large literature, but heterogeneous; newer PRIME work substantially industry-linked
Thermage FLX	Monopolar RF	Moderate for FLX; larger historical Thermage literature	Wrinkles/rhytids in cited FLX clearance	Do not equate older Thermage evidence with current FLX; modern laxity trial remains underway
Sofwave	Parallel-beam ultrasound	Moderate but smaller; several direct prospective studies	Explicit eyebrow and lax submental/neck lifting	Small samples; limited long-term independent replication
Morpheus8	Fractional RF microneedling	Limited-to-moderate branded tightening evidence; stronger RFMN class evidence	Soft-tissue coagulation/contraction	Review and combination therapy dominate branded literature located
Potenza	RF microneedling	Limited device-specific tightening evidence located	Electrocoagulation and haemostasis	Published Potenza studies located mainly acne/scars/melasma rather than primary lifting

The strongest AI-research lesson

The question “Does HIFU/RF/RF microneedling work?” is too broad for a major capital decision. The useful question is: “What evidence supports this exact model, for this exact indication, at this exact protocol — and how independent is that evidence?”

Three findings deserve particular attention:

- Ultherapy has the deepest recognizable device-specific trail among these five, but Ultherapy evidence should not be treated as equivalent to evidence for every generic HIFU platform, and PRIME-specific evidence is still relatively young.
- Thermage demonstrates model-generation specificity: the brand has a long history, yet a large manufacturer-sponsored randomized controlled study designed specifically to establish Thermage FLX lifting/tightening outcomes remains underway in 2026 [7].
- For RF microneedling, a 2026 systematic review was strongly positive, yet two authors worked in Global Medical Affairs for Jeisys and another was a Jeisys speaker [13]. Separately, the FDA issued a 2025 safety communication describing serious reported complications with certain RF-microneedling uses [14].

2. How this review was conducted

This was a targeted evidence-mapping exercise designed to simulate the due diligence a clinic owner could commission from AI before engaging seriously with a device salesperson. It was not designed to meet PRISMA standards or provide an exhaustive count of every paper published.

Source priority: PubMed/PMC, FDA 510(k) summaries/databases, ClinicalTrials.gov, MHRA/GOV.UK guidance, then manufacturer sites only for current claims, product descriptions or UK availability.

Evidence hierarchy: systematic review/meta-analysis → randomized/controlled study → prospective study → retrospective/case series → narrative review → manufacturer material/KOL opinion.

Device-specificity rule: a study was treated as device-specific only where the branded platform/model could be identified. Technology-class evidence was not automatically transferred to a branded device.

Conflict review: employment, sponsorship, consultancy, honoraria and speaker roles were treated as context that can affect confidence, not as proof that findings are invalid.

Safety rule: spontaneous adverse-event databases and FDA safety communications identify possible signals but cannot reliably calculate incidence without denominators, verification and causal assessment.

A critical UK point

For Great Britain, medical devices placed on the market must be registered with the MHRA and conform to the UK Medical Devices Regulations 2002. CE-marked devices continue to be accepted under transitional arrangements that vary by regulatory route. MHRA registration itself is not approval or endorsement [20–21].

3. Evidence language used in this report

Description	Meaning
Relatively strong	Multiple device-specific studies and/or synthesis, some independent replication, but still subject to limitations of aesthetic-device research.
Moderate	Direct clinically relevant evidence exists, but sample size, follow-up, independence, comparators or model specificity limit certainty.
Limited	Some direct evidence exists, but too little high-quality device-specific work was located to support broad claims confidently.
Insufficient	The targeted search did not locate adequate evidence for the specific claim; this does not prove the device is ineffective.

4. Ultherapy / Ultherapy PRIME

Bottom line

Among these five platforms, Ulthera/Ultherapy has the deepest recognizable branded evidence trail for non-invasive lifting. Caveats: heterogeneous study designs, commercial involvement in parts of the literature, and a much smaller direct evidence base for the newest PRIME generation.

Regulatory record

The FDA's 2026 Ulthera clearance (K260618) includes explicit indications to lift the eyebrow and lift lax submental and neck tissue. The DeepSEE component visualises tissue to help confirm coupling and treatment depth [5].

Clinical evidence

- A systematic review/meta-analysis of MFU-V included dozens of studies and reported high proportions of investigator- and patient-assessed improvement. Heterogeneity was substantial, and “any improvement” should not be confused with a large anatomical lift [1].
- A prospective lower-face study of 103 adults found blinded-reviewer improvement in 58.1% at 90 days. Outcomes were less favourable in participants with BMI >30; pain scores were roughly 5.7–6.5/10 depending on area [2].
- An independent 50-patient Indian Ulthera study reported improvement through one year and declared no financial interest [3].
- Ultherapy PRIME has emerging direct data, but targeted PRIME publications located included Merz sponsorship, honoraria and/or prior consultancy relationships. That does not negate the results; it reduces the amount of fully independent replication.

Safety

A 2025 systematic safety review found published MFU-V studies mostly reported transient erythema, oedema and pain, with one published subcutaneous-atrophy case. The same review extracted 106 FDA MAUDE reports involving Ulthera, including lipoatrophy, neurological symptoms and scarring. The authors stressed that MAUDE reports are anecdotal/largely unverified and cannot establish incidence [4].

What a buyer should not assume

- Evidence for Ultherapy/MFU-V is evidence for every generic HIFU machine.
- A responder rate tells you the magnitude of lift.
- Legacy Ulthera evidence automatically establishes identical outcomes for every PRIME configuration/protocol.
- MAUDE data can be used to calculate the probability of a complication.

5. Thermage FLX

Bottom line

Thermage has a long clinical history as a monopolar-RF platform. For the current FLX generation, useful direct evidence exists, including an independent randomized split-face comparison, but modern generation-specific lifting evidence is thinner than the historical brand reputation may imply.

Regulatory wording matters

The FDA 510(k) for Thermage FLX (K170758) describes non-invasive treatment of periorbital wrinkles/rhytids and wrinkles/rhytids generally. It does not use the same explicit “lift lax submental and neck tissue” wording seen in the Ultherapy and Sofwave clearances cited here [8].

Direct FLX evidence

- A 2025 prospective randomized split-face single-blind trial in 22 Asian women compared Thermage FLX with another monopolar-RF platform. It used objective measures and blinded dermatologist assessments. Both sides improved over 8 weeks; Thermage FLX pain was high in that protocol (mean about 8.4/10). The paper reported no funding and no conflicts [6].
- Combination studies using Thermage FLX plus another energy device can demonstrate a programme effect but cannot isolate Thermage’s contribution.
- A manufacturer-sponsored randomized multicentre controlled study of about 164 participants is specifically designed to test Thermage FLX for lines/wrinkles and laxity of the face, neck, abdomen and upper arms. ClinicalTrials.gov lists completion into 2027 and no results posted at the time of review [7].

Why the ongoing trial matters

It exposes the difference between “Thermage has been studied for years” and “the current FLX generation has modern controlled evidence for this exact lifting claim.” Those statements are related, but not identical.

What a buyer should not assume

- Older Thermage-generation studies automatically validate FLX outcomes.
- Wrinkle-clearance language is equivalent to an explicit lifting indication.
- Combination-treatment studies prove the independent contribution of Thermage FLX.
- An 8-week study establishes 12–24 month durability.

6. Sofwave

Bottom line

Sofwave has direct device-specific studies and explicit FDA lifting indications. Its evidence base is smaller than Ultherapy's, and several studies are small, uncontrolled or manufacturer-funded; independent replication and longer follow-up remain important gaps.

Regulatory record

FDA clearance for Sofwave includes improvement of facial lines/wrinkles and lifting of the eyebrow and lax submental/neck tissue in adults. This is directly relevant to a skin-lifting proposition rather than merely generic rejuvenation.

Direct clinical evidence

- A 2023 study enrolled 36 participants and used Antera 3D to measure nasolabial-fold and marionette-line depression volume at 1 and 3 months. Significant changes were reported; mean pain was 6.64/10 and no adverse events were reported [9].
- A prospective trial of 15 people aged 40–69 used two sessions and reported improvement in eyebrow, submental and neck laxity persisting to six months; mean pain was 5.6/10 [10].
- A 2026 Asian prospective study reported improvement in eyebrow elevation and facial wrinkles at 3 months, with some effects sustained to 9 months. It was funded by Sofwave Medical Ltd [11].

Pivotal/regulatory-study caveat

The pivotal evidence supporting lifting indications was prospective and multicentre but open-label/self-controlled rather than a sham-controlled or large head-to-head technology comparison. That is useful evidence, but not the same as a large blinded randomized comparative trial.

What a buyer should not assume

- A statistically significant 3D metric necessarily represents a large patient-visible lift.
- Two small prospective trials establish broad generalisability across ages, ethnicities and degrees of laxity.
- A manufacturer-funded longer-term study is equivalent to multiple independent replications.

7. Morpheus8

Bottom line

Morpheus8 is highly visible commercially and RF microneedling has a growing evidence base, but the branded skin-tightening evidence located was less robust than market prominence might suggest. Much Morpheus8-specific literature found was review material or combination therapy.

Regulatory record

The FDA clearance examined for the InMode system with Morpheus8 90 states that it is intended for dermatological procedures where coagulation and contraction of soft tissue or haemostasis is needed. At higher per-pin energy settings, use is limited to Fitzpatrick I–IV [15].

What the branded literature looks like

- A 2022 peer-reviewed article specifically reviewed facial applications of Morpheus8. It is useful for mechanism and applications, but is a review rather than a new randomized efficacy trial; one author disclosed consultancy for InMode Aesthetics [12].
- A small prospective recurrent-jowl/neck study after facelift combined AccuTite with Morpheus8; only nine patients completed follow-up. The two-modality design cannot establish the independent Morpheus8 effect.
- Other branded publications located also combine Morpheus8 with FaceTite/AccuTite or discuss broader RF-assisted procedures, complicating attribution.

Class-level RFMN evidence is stronger

A 2026 systematic review of RF microneedling included 22 studies (20 in synthesis; 558 participants) and reported consistent aesthetic improvement, high satisfaction and predominantly mild transient adverse effects. Two authors worked in Global Medical Affairs at Jeisys Medical and another was a Jeisys speaker [13]. Jeisys manufactures RF-microneedling devices but not Morpheus8; using this review as direct proof of Morpheus8 would be category-to-brand extrapolation.

Safety changed the purchasing conversation

In October 2025 the FDA issued a safety communication about certain uses of RF microneedling after reports of serious complications including burns, scarring, fat loss, disfigurement and nerve damage, sometimes requiring medical or surgical intervention [14]. The communication is class-level and does not provide Morpheus8-specific incidence.

8. Potenza

Bottom line

Potenza is a versatile RF-microneedling platform, but in this targeted search the strongest peer-reviewed Potenza-specific papers located focused on acne, acne scars and melasma rather than controlled facial-lifting outcomes. If the purchase case is mainly skin tightening, that evidence gap matters.

Regulatory record

The FDA indication examined for Potenza (K231287) is broad electrosurgical wording: dermatologic and general surgical procedures for electrocoagulation and haemostasis [16]. It does not itself establish a specific FDA lifting indication.

Potenza-specific papers located

- A 2026 retrospective study of 50 acne patients reported improvement after three Potenza treatments, but acne efficacy is not evidence of clinically meaningful lifting [17].
- A 2026 retrospective melasma study of 29 women did not find a statistically significant median mMASI change overall ($p=.16$), demonstrating that branded-device research is not uniformly positive — but again this is not a tightening study [18].
- A prospective randomized split-face study of 20 subjects evaluated Potenza with/without a picosecond laser for acne scars. It supports RF-microneedling activity in scars, not a primary lifting claim [19].

Purchasing implication

If a distributor proposes Potenza mainly for non-surgical lifting, ask for the strongest peer-reviewed trials using Potenza itself with tightening/lifting as the primary outcome. Do not accept the general RF-microneedling literature as a complete substitute.

9. Head-to-head evidence map

Question	Ultherapy / PRIME	Thermage FLX	Sofwave	Morpheus8	Potenza
Exact branded tightening/lifting studies	Many for legacy Ulthera; fewer PRIME	Some direct FLX; larger historical literature	Several direct prospective studies	Few clean standalone tightening trials located	Few/none robust primary tightening trials located
Controlled evidence	Exists in broader MFU-V field; many studies non-randomized	Small split-face FLX study; larger trial ongoing	Pivotal self-controlled + small prospective studies	Class-level RFMN RCTs; branded evidence thinner	Class-level RFMN RCTs; Potenza studies found mainly other indications
Independent replication	Moderate	Limited-to-moderate for FLX	Limited-to-moderate	Limited branded	Limited for tightening
Longer follow-up	Some 12-month data	Historical data; current FLX controlled data developing	Some 6–9 month data	Mostly short/moderate; combinations	Tightening-specific durability unclear
FDA lifting wording	Explicit	Wrinkle/rhytid wording in cited clearance	Explicit	Soft-tissue contraction wording	Electrocoagulation/haemo stasis wording
Main evidence risk	Generic-HIFU extrapolation; PRIME commercial links	Historical-brand evidence mistaken for FLX evidence	Small samples; limited long-term independent replication	RFMN class evidence mistaken for Morpheus8 proof	RFMN class/non-tightening evidence mistaken for lifting proof

“Few/none located” means not identified in this targeted search; it is not proof that no such study exists. Suppliers should be invited to submit additional peer-reviewed evidence for appraisal.

10. Marketing claim audit

Claim	Evidence question	Why it matters
“Clinically proven”	Which exact model, handpiece/tip and indication was studied? Peer reviewed?	Technology-class evidence can be much stronger than exact-device evidence.
“FDA approved”	Approved, 510(k)-cleared, or registered? What is the exact indication wording?	These concepts are not interchangeable.
“One treatment lasts 12–24 months”	Show the exact study and retention at 12/18/24 months.	Most literature is shorter term.
“Non-surgical facelift”	What objective displacement/laxity change occurred?	Aesthetic improvement scales do not establish surgical equivalence.
“Works on all skin types”	Show outcomes/adverse events by Fitzpatrick type for this model/settings.	Risk and outcomes can vary with settings and tissue/skin characteristics.
“RF microneedling is proven”	Which studies used this exact branded device?	Strong class evidence does not validate every commercial platform.
“No downtime / no risk”	Provide post-market safety data and escalation pathways.	Rare complications can be missed by small trials.

11. Conflict-of-interest and independence check

Industry involvement is common and often necessary in device research. The correct response is not to discard sponsored research; it is to track whether results are reproduced outside the manufacturer’s commercial ecosystem.

Evidence pattern	Confidence implication
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Evidence pattern	Confidence implication
Manufacturer-funded single-arm study only	Useful early signal; lower confidence for broad purchasing claims.
Sponsored pivotal study + independent prospective replication	Stronger; compare effect magnitude and safety across sites.
Independent randomized comparator + objective measures	High-value evidence even if sample is modest.
Systematic review authored/employed by manufacturer in same technology class	Still informative, but conflict should be visible in the appraisal.
KOL testimonial / white paper without peer review	Commercial information, not equivalent to clinical evidence.

As an example

The 2026 RF-microneedling systematic review is positive and includes 22 studies, but two authors were Jeisys Medical employees and another was a Jeisys speaker. A superficial search may stop at “systematic review says it works.” A deeper AI review asks who wrote it, who funded it, which devices were studied, and whether findings have independent replication.

12. Safety due diligence

Risk domain	Ultrasound / MFU-V	Monopolar RF	RF microneedling
Typical transient effects	Pain, erythema, oedema, tenderness	Pain/heat, erythema, oedema	Erythema, oedema, pain, pinpoint bleeding
Signals to investigate	Neurological symptoms, scarring, unwanted atrophy/lipoatrophy	Burns, prolonged pain, scarring	Burns, scarring, fat loss, disfigurement, nerve injury, pigmentary change, infection
Source beyond trials	MAUDE/vigilance + systematic safety reviews	Manufacturer PMS/vigilance + MAUDE where applicable	FDA 2025 safety communication + MAUDE/vigilance + manufacturer PMS
Do not infer from reports	Incidence or causality	Incidence or causality	Incidence or device-specific risk without denominator/verification

13. UK regulatory checks before purchase

US FDA records are useful because they expose exact intended-use wording. They are not a substitute for UK due diligence.

1. Ask for the exact model and catalogue/version number being supplied in Great Britain.
2. Verify the device is lawfully placed on the Great Britain market and registered with the MHRA where required. MHRA guidance states that all medical devices placed on the GB market must be registered; registration itself is not an approval or endorsement [20].
3. Verify the conformity route and marking (UKCA and/or a currently accepted CE route). Current GB transitional arrangements allow certain CE-marked devices through 2028 or 2030 depending on the underlying EU legislation [21].
4. Check that marketed indications match the manufacturer's intended purpose and instructions for use.
5. Ask who the UK Responsible Person is if the manufacturer is based outside the UK.
6. Request post-market surveillance information and the incident-reporting pathway to the manufacturer/MHRA.

14. Supplier challenge checklist

Give the same request to every supplier so sales presentations become comparable.

1. Provide the three strongest peer-reviewed studies using the exact model you are selling us, with skin tightening/lifting as the primary indication.
2. For each paper, identify sample size, comparator, blinding, follow-up, objective outcome measures and funding source.
3. Which studies were conducted without manufacturer funding, supplied equipment, consultancy, honoraria or speaker relationships?
4. Which results have been independently replicated by a separate research group?
5. What is the exact UK intended purpose and conformity route for this model?
6. What post-market adverse-event data do you hold for burns, scarring, neuropathy, fat loss/atrophy, pigment change, infection and prolonged pain?
7. What evidence supports the claimed duration of effect and need for repeat treatment?
8. What patient characteristics predict poor results or higher risk?
9. What is the full cost per treatment: tip/consumables, service allocation, practitioner time, anaesthetic and disposables?
10. If the handpiece/system fails, state warranty, replacement lead time, loan-unit policy and typical repair cost.
11. What is the expected residual value after three and five years and can ownership/software/service agreements transfer?
12. Provide three UK clinic references with comparable patient demographics and at least 24 months' ownership.

15. Commercial due diligence: turn evidence into a buying decision

A clinically credible device can still be a poor investment. Clinical evidence should feed into a separate commercial model rather than ending with “the machine works”.

Variable	Clinic input	Why it matters
Capital/finance cost	£_____	Include interest/lease fees and deposit opportunity cost.
Consumable/tip cost per treatment	£_____	Some platforms create substantial variable cost.
Practitioner + room cost	£_____	Use loaded hourly cost, not salary alone.
Realistic achieved price	£_____	Use actual price after packages/discounts, not list price.
Contribution per treatment	Price – direct/variable cost	Amount available to repay capital and overhead.
Realistic treatments/month	_____	Base on current database/local demand, not supplier forecast.
Break-even treatments	Capital ÷ contribution	Shows the utilisation burden.
Months to capital payback	Break-even ÷ monthly volume	Compare with warranty, device life and finance term.
Alternative use of capital	£_____ expected return	Compare with staff, marketing, rooms, CRM/automation or other services.

Commercial figures are deliberately blank

Purchase price, consumables, service, finance, treatment pricing and resale values vary by distributor, negotiation and date. Obtain them in writing from each supplier and test all devices in the same model.

16. What AI added beyond a normal web search

The useful work was not simply finding papers; it was repeatedly changing the question as new evidence appeared.

Initial claim	Deeper AI question	Finding exposed
"HIFU is well studied"	Was the evidence on Ultherapy/MFU-V or generic HIFU?	Technology and device evidence are not interchangeable.
"Thermage has decades of research"	How much is specifically current FLX?	A modern FLX laxity trial remains underway.
"Sofwave is FDA-cleared for lifting"	What design produced the evidence?	Direct support exists, but studies are smaller/often self-controlled.
"RFMN has a positive systematic review"	Who authored it and which devices were studied?	Industry relationships and category-to-brand extrapolation become visible.
"Morpheus8 tightens"	Where are clean branded standalone lifting trials?	Much branded literature located is review/combination treatment.
"Potenza tightens"	Which Potenza trials have lifting as the primary endpoint?	Targeted search found more research in acne/scars/melasma.
"RFMN is safe"	What changed after trials were published?	FDA issued a 2025 safety communication on serious reported complications.

Key message:

Don't ask AI: "Which machine should I buy?" Ask it to build the case against the purchase as well as the case for it. Make it trace sales claims back to the exact device, study design, funding, regulatory wording, safety data and commercial assumptions.

17. Conclusions

Ultherapy / Ulthera: the most substantial recognizable branded lifting evidence trail among these five, with heterogeneity, commercial involvement in parts of the literature and a smaller evidence base for PRIME specifically.

Thermage FLX: credible current-generation evidence exists, including a small independent randomized split-face study, but buyers should separate the long Thermage history from evidence specifically validating FLX for modern lifting claims. A large sponsored controlled study remains underway.

Sofwave: direct prospective studies and explicit lifting indications are strengths; the evidence base remains smaller, with modest sample sizes and a need for more long-term independent replication.

Morpheus8: the RFMN class has expanding evidence, but direct branded standalone tightening evidence located was less extensive than market prominence might imply; combination studies and class-level evidence must be separated.

Potenza: the targeted search found peer-reviewed branded research, but much of it related to acne, scars and melasma rather than primary lifting. A clinic buying mainly for tightening should require more device-specific lifting evidence.

Overall

This report does not identify a universal "best" machine. It shows how AI can make a high-value purchasing discussion much harder for marketing to dominate: evidence can be separated by exact device, generation, endpoint, independence, regulatory wording and post-market safety before the commercial numbers are considered.

18. Key sources

Links checked during research on 21 September 2026.

1. Systematic review/meta-analysis of MFU-V, PMID 39540440. [Link](#)
2. Prospective Ulthera lower-face study (103 enrolled), PMID 24990884. [Link](#)
3. Shome D, et al. Use of Micro-focused Ultrasound for Skin Tightening of Mid and Lower Face. PMID 32537285. [Link](#)
4. Systematic review of MFU-V safety plus FDA MAUDE analysis, PMID 39625163. [Link](#)
5. FDA 510(k) K260618 — Ulthera System / DeepSEE. [Link](#)
6. Roh H, et al. Monopolar RF comparison including Thermage FLX. PMID 41331720. [Link](#)
7. ClinicalTrials.gov NCT07187297 — Thermage FLX controlled study. [Link](#)
8. FDA 510(k) K170758 — Thermage FLX. [Link](#)
9. Hongcharu W, et al. Parallel-beam ultrasound for skin tightening. PMID 36757157. [Link](#)
10. Gold MH, Biron J. Non-focused ultrasound parallel beams for facial laxity. PMID 38031530. [Link](#)
11. Asian prospective non-focused ultrasound study, 2026; PMID 42226470. [Link](#)
12. Hendricks AJ, Farhang SZ. Dermatologic facial applications of Morpheus8. PMID 35916259. [Link](#)
13. Kumar N, et al. Radiofrequency Microneedling for Facial Rejuvenation: A Systematic Review. PMID 41947517. [Link](#)
14. FDA Safety Communication: Potential Risks with Certain Uses of RF Microneedling, 15 Oct 2025. [Link](#)
15. FDA 510(k) K240017 — InMode System with Morpheus8 90. [Link](#)
16. FDA 510(k) K231287 — POTENZA. [Link](#)
17. Potenza RF microneedling acne study, 2026; PMID 42582510. [Link](#)
18. Potenza RF microneedling melasma study, 2026; PMID 42094857. [Link](#)
19. Randomized split-face Potenza/picosecond acne-scar study; PMID 41405932. [Link](#)
20. MHRA/GOV.UK: Register medical devices to place on the market, updated 20 July 2026. [Link](#)
21. MHRA/GOV.UK: Regulating medical devices in the UK, updated 20 February 2026. [Link](#)

Scope and limitation

This report supports purchasing questions and due diligence. It does not replace a formal systematic review, specialist device-regulatory advice, local governance, insurer requirements, manufacturer instructions for use, or independent verification of key studies before clinical implementation.