

When the Original Business Model Stops Working

Pricing & Regulatory Strategy | Strategic decision memo

Executive summary

Two external constraints—a hospital capital-spending freeze and an FDA request for additional generalizability evidence—create timing risk rather than a fundamental technology problem. The proposed response is to preserve market access and regulatory credibility through two reversible moves: shift from an upfront CAPEX licence to pay-per-scan OPEX pricing, and pursue a constrained measurement-assurance release alongside a multi-site validation programme.

1. The commercial constraint: CAPEX to OPEX

Recent federal budget legislation has contributed to a freeze in hospital capital-equipment and enterprise-software spending for FY 2026–27. The company's \$50K annual upfront licence is therefore structurally difficult to approve, independent of product quality or demand.

The strategic response is to move from a capital software purchase to a clinical-efficiency utility embedded in daily ultrasound operations. The company would monetise time saved per scan rather than software ownership, aligning the price with an operational input that can be purchased through departmental budgets.

Commercial model shift

- Replace the \$50K upfront licence with pay-per-scan pricing.
- Bill monthly and position the expense as OPEX.
- Enable departmental purchasing, reducing dependence on capital-committee cycles.
- Let revenue scale with clinical utilisation rather than procurement timing.

Unit economics (order-of-magnitude)

- Prior annual contract value (ACV) target: \$50K per hospital.
- Reference site: 2,500 scans per year.
- Revenue parity: $\$50K \div 2,500 = \$20$ per scan.
- At \$15 per scan: approximately 3,300 scans per year to reach \$50K.
- At \$25 per scan: approximately 2,000 scans per year to reach \$50K.

This accepts lower revenue from small sites in exchange for greater upside at high-volume sites and a more deployable model while capital spending is constrained.

Explicit trade-off

The model increases dependence on scan volume and reduces revenue certainty. The strategic judgement is that variable revenue linked to adoption is preferable to no adoption while CAPEX purchasing is blocked.

2. The regulatory constraint: resolving the FDA hold

The FDA has issued a hold letter on the product's 510(k), requesting additional demographic generalizability evidence across three BMI-diverse clinical sites. A standard prospective validation study would take approximately six months, pushing the launch beyond Q4 and putting a major health-system contract estimated at \$3.2M ARR—and the timing of the Series B process—at risk.

The objective is to resolve the hold while preserving regulatory credibility, avoiding irreversible changes to the product or business model, and maintaining a fundable trajectory.

Three paths considered

Option 1 — Integrate as an accessory module

Deploy the product within an already-cleared biometry platform. This could reduce regulatory scope, but would introduce revenue sharing, weaken standalone pricing power, and create dependency on an external OEM's roadmap. The option is reversible, but execution risk is moderate and the timeline is uncertain.

Option 2 — Release a scope-constrained measurement-assurance mode

Configure the system to validate clinician-entered measurements and flag deviations without producing autonomous outputs. This preserves clinician-in-the-loop positioning, maintains workflow value, and may enable continued commercial deployment with modified positioning. The trade-off is temporarily reduced feature differentiation until validation is complete.

Option 3 — Establish a multi-site validation consortium

Coordinate academic and high-volume clinical sites under a unified protocol. The company retains its intellectual property while coordinating integration and study execution. This defers some near-term revenue and adds coordination costs, but generates durable FDA-grade evidence and strengthens the long-term regulatory and competitive position.

3. Recommended response: a reversible dual track

Track 1 — Near-term continuity

Release measurement-assurance mode with constrained claims, targeting Q4 2026. Clinicians retain final control; autonomous claims remain limited until validation is complete. The intention is to preserve workflow value and the customer relationship.

Track 2 — Long-term regulatory evidence

Launch a structured multi-site validation consortium, with a \$600K investment and a 6–9 month timeline. The target for full clearance is Q2 2027.

The dual-track proposal aims to launch in Q4 with modified positioning and move toward full autonomous functionality in Q2 2027, subject to the required evidence and regulatory outcome. It is designed to preserve revenue continuity without abandoning the longer-term regulatory roadmap.

4. Pay-per-scan model: illustrative site economics

- Small site: 1,500 scans/year × \$20 = \$30K/year.
- Mid-sized site: 2,500 scans/year × \$20 = \$50K/year.
- Large site: 5,000 scans/year × \$20 = \$100K/year.

- Minimum annual usage commitments can help protect baseline revenue.

The upside is improved access while capital spending is constrained, potentially faster sales cycles, and stronger economics at high-volume sites. The trade-off is greater volume dependence at smaller sites.

5. Decisions required

1. Approve the reversible measurement-assurance launch: constrained release, Q4 2026 target, and modified claims.
2. Authorise the multi-site validation consortium: \$600K investment, 6–9 month timeline, and target of full FDA clearance.
3. Approve the pay-per-scan commercial model: \$15–\$25 per scan, replacing the \$50K upfront licence; retraining is required and revenue variability is accepted.
4. Confirm continuation of the Series B process and seek term-sheet confirmation while the revised execution plan proceeds.

Decision logic

The plan prioritises regulatory credibility, reversible execution, revenue continuity, and fundability under external constraints. The stated commercial objective is to protect a \$3.2M ARR customer contract and target a Q4 2026 launch while investing \$600K in the validation path.

References

U.S. Food & Drug Administration — 510(k) Submission Process: <https://www.fda.gov/medical-devices/premarket-notification-510k/510k-submission-process>

CMS Fact Sheet — FY 2024 Hospital Inpatient Prospective Payment System and Long-Term Care Hospital Prospective Payment System: <https://www.cms.gov/newsroom/fact-sheets/fy-2024-hospital-inpatient-prospective-paymentsystem-ipp-and-long-term-care-hospital-prospective-0>