

SURGIVISION AI

A source-backed foundation for the next prototype

Prepared 11 October 2026. Focus: cardiothoracic surgery. Comparison markets: United States, European Union, United Kingdom and India.

Recommended first product

Start with a **CT-based thoracic anatomy review and training workspace**, centered on lung segmentectomy. Build a clinician-reviewed 3D case library with linked CT slices, editable anatomy, annotations and optional VR. Treat patient-specific clinical planning as a separate, regulated development track.

What the research establishes

Genuine 3D imaging datasets and reusable imaging tools exist. Clinical studies support feasibility and spatial review, but patient-outcome benefits differ by population and endpoint. A visually convincing demo is not evidence that the product is safe for surgery. [\[02\]](#) [\[04\]](#) [\[07\]](#) [\[10\]](#) [\[11\]](#)

The startup opportunity is specific, not empty

Established products already offer thoracic 3D models and procedural planning. SURGIVISION needs a measurable advantage in case preparation, review effort, usability, deployment or economics; 'AI + VR' alone is not a defensible differentiator. [\[26\]](#) [\[29\]](#) [\[31\]](#)

How to read this brief

Linked numbered references identify the supporting primary or official source. Recommendations, proposed study designs and commercial hypotheses are labeled as such. Vendor pages verify described features, not clinical efficacy. Several clinical findings were appraised at abstract level, not by full-text risk-of-bias review.

Scope: targeted desk research, not an exhaustive systematic review, clinical advice, regulatory opinion or investment recommendation. No patient dataset was downloaded, no clinician was contacted, and the existing demo was not changed in this research pass.

Choose One Clinical Workflow

Clinical context

WHO estimates 2.5 million new lung-cancer cases and 1.8 million deaths worldwide in 2022. These are disease-burden figures, not the number of surgical candidates or paying customers. Resection is one treatment option and depends on stage and clinical assessment. [01]

Candidate	Initial fit	Key constraint
Lung anatomy / segmentectomy	Recommended first focus. Review nodules relative to lobes, bronchi and vessels; support retrospective case discussion and training.	Public nodule/organ data does not automatically supply reliable segmental arteries, veins or surgical borders.
Adult cardiac anatomy	Useful second case-library track: chambers, great vessels and chest relationships.	Routine chest CT is not automatically suitable for coronary, valve or motion analysis.
Structural-heart planning	Later specialist module. TAVI evidence is relevant but distinct from open surgery. [07]	Requires appropriate acquisition, task-specific measurement validation and a tightly defined intended use.
Live surgical navigation	Defer beyond the initial product.	Registration, tracking, organ deformation and intraoperative hazards add major validation requirements.

Proposed early intended-use statement

'An educational and research workspace for qualified users to explore de-identified cardiothoracic CT cases, inspect reviewed anatomical models and record case-discussion annotations. It is not intended to diagnose disease, select treatment, guide instruments or determine clinical surgical margins.'

Do not blur the two tracks

If the software is actually used to make a patient's operative plan, its real intended purpose and use may bring it into medical-device regulation. A 'demo' or 'research only' label is not a substitute for the appropriate assessment and controls.

The focus on complex lung anatomy is a product recommendation, not a universal treatment recommendation. A 2024 international Delphi report favored 3D reconstruction particularly for complex segmentectomy; it is expert consensus, not proof that every case benefits. [09]

Thoracic Evidence: Benefits And Limits

Study / design	Reported finding	What it does not establish
PulmoVR pilot, 2021 10 patients; prospective observational study [02]	VR was used as supplementary planning; the surgical strategy changed in 40% of cases.	No randomized comparison. A changed plan is not necessarily a better outcome, and this is not SURGIVISION validation.
Bakhuis et al., 2023 50 consecutive cases; CT review followed by VR [03]	Plans changed in 52%; pathology showed radical resection in 49/50 cases (98%).	Sequential review and no contemporaneous randomized control leave review-order and selection effects. Outcomes cannot be attributed to VR alone.
DRIVATS, 2024 191 patients; 3-hospital RCT [04]	Median operative time was 100 minutes in both arms ($P=0.82$). Postoperative complication incidence did not differ significantly ($P=0.52$).	Population: small peripheral nodules not reaching segment borders. Compared 3D CT reconstruction with standard CT, not VR with desktop 3D.
Liao et al., 2026 144 patients; randomized trial [05]	Key-phase time: 75.78 vs 95.74 minutes ($P<0.001$). Unexpected events and adequate pathological margins favored 3D. Total operative time and postoperative complications did not significantly differ.	Recent single-center report; selected operative phase is not total operating-room time. Does not isolate immersion, AI, or this product's effect.

Interpretation

The findings justify testing a well-defined workflow, not promising universal complication reduction. Case complexity, surgeon experience, the comparator and the chosen endpoint all matter. Larger controlled studies and small feasibility series answer different questions.

Claim discipline

Use: 'We are testing whether reviewed 3D anatomy improves spatial understanding and case preparation.' Avoid: 'Our AI makes lung surgery safer,' 'reduces blood loss,' or 'guarantees clear margins' until the actual product supports those claims with appropriate evidence.

Methods note: study rows above are based on indexed abstracts. Obtain and independently appraise full protocols, endpoint definitions, missing-data handling, adverse events and conflicts of interest before using effect sizes in a clinical or investor claim.

Cardiac Evidence Is A Separate Track

Study	Finding	Implication
Adult cardiac VR, 2020 6 patients; 5 surgeons [06]	Initial experience found the supplementary visualization potentially useful for planning complex/minimally invasive surgery.	Feasibility and questionnaire evidence only. No comparative complication, survival or time benefit established.
TAVI planning RCT, 2026 140 patients [07]	VR supplemented 3mensio planning. Spatial understanding favored VR; procedural data did not significantly differ. Access-site bleeding was lower in the VR arm (P<0.05); stay and postprocedural echo did not significantly differ.	Relevant to structural-heart intervention, not a blanket finding for CABG or valve surgery. Full-text analysis is needed for effect magnitude, endpoint hierarchy and multiplicity.
Congenital-heart education RCT, 2021 51 participants [08]	The same heart models were viewed in VR or on desktop. Knowledge-score improvement did not differ significantly (P=0.11), although subjective experience favored VR.	Do not assume immersive display improves learning merely because users prefer it. Test retention and objective tasks against a good desktop comparator.

Proposed cardiac expansion

After the thoracic pipeline works, add reviewed cardiac anatomy cases. For clinical applications, select one procedure and acquisition protocol with a cardiac imaging specialist. Specify chambers and vessels of interest, relevant contrast/cardiac phase, required measurements, and conditions where the model cannot be trusted.

Static geometry is not physiology

A single-volume model does not establish heart motion, tissue compliance, coronary flow, valve-device behavior or bleeding risk. Animation based on an arbitrary heartbeat should be labeled illustrative. Patient-specific motion requires suitable time-resolved data and a separately validated method.

A fair VR experiment

Use the same scan and reviewed segmentation in desktop 3D and headset VR. Otherwise any gain may come from better segmentation or a second review, not from immersion. Record task accuracy, review time, discomfort and critical errors.

Genuine Data For A Real 3D Prototype

Resource	Verified data / license	Recommended use and gaps
LIDC-IDRI [10]	1,010 patients. DICOM images and radiologist XML annotations. Download table lists CC BY 3.0 for images and annotations.	First candidate for a lung-nodule case. Reader annotations are not automatically surgical truth or complete bronchovascular segmentation. Keep provenance and attribution.
TotalSegmentator CT v3.0.0 [11] [12]	1,939 CT images; 117 labeled structures. Published 10 Sep 2026. 37.4 GB archive. Official API metadata: CC BY 4.0.	Useful for anatomy and reviewed masks. Select a complete chest case with suitable quality. Dataset labels are not equivalent to verified segmental anatomy, pathology or surgical outcomes.
ASOCA [13]	Organizer describes 40 annotated training CCTA scans and 20 test scans. Post-challenge access is via repository/request routes. Commercial permission not verified here.	Candidate for a later coronary research module. Do not put cases into a public startup demo or commercial training pipeline until current terms permit it.

Licenses are separate layers

Audit the dataset, annotations, model weights, software and any derived asset independently. CC BY licenses require attribution and attention to other applicable rights. 'Publicly accessible' is not the same as permission for every commercial use. [\[34\]](#)

TotalSegmentator lists 'total' and 'lung_vessels' as open Apache-2.0 tasks, but high-resolution heart-chamber and coronary tasks appear in its separately licensed group. Verify the exact pinned release/task and weight terms; do not inherit a license from the project name. [\[14\]](#)

Next data action

Acquire a small, explicitly permitted sample from the official owner. Preserve the citation, version, license and checksum. Inspect the volume and masks; then obtain specialist review. This brief identifies sources but has not downloaded or medically verified a demo case.

Build A Traceable Imaging Pipeline

Input and geometry

Use actual DICOM volumes or an appropriately converted NIfTI/NRRD volume with its spatial affine. DICOM defines pixel spacing, image position and direction cosines. A JPEG collage lacks enough verified geometry to serve as a metric patient reconstruction. [\[15\]](#)

Stage	Implementation proposal	Required check
Ingest	Read-only source storage; DICOM reader/converter; reject localizers, mixed series and unsupported acquisitions.	Series identity, physical slice order, spacing, orientation, pixel values and missing slices.
Segment	Begin with existing annotated masks and manual editing. Evaluate a pinned automatic model later.	Source/model label distinctions; every critical structure reviewed in multiplanar CT.
Review	3D Slicer as a research workstation; reviewers approve or correct masks.	Record reviewer, edits, timestamp, failure reason and source series.
Render	VTK-based surface generation; controlled mesh simplification; Three.js desktop viewer; optional later OpenXR headset build.	Explicit mm-to-viewer conversion, coordinate transforms, left/right labels and mesh/volume alignment.
Record	Versioned case package: scan, masks, meshes, annotations and report manifest.	Reproducible provenance, integrity hashes, approved state and no unsupported clinical outputs.

3D Slicer supports editable segmentation workflows and external-viewer exports. Its BSD-style license permits commercial use, but Slicer itself is not an FDA-approved product. Its capabilities and license do not authorize a clinical SURGIVISION system. [\[16\]](#) [\[17\]](#)

Suggested case manifest

Store: case ID, dataset/version/license, source-series ID, spacing, orientation/affine, model/task/version, mask provenance, reviewer status, mesh transform, units, exclusions and checksums. Mark unavailable structures explicitly instead of inventing them.

Architecture is a proposal, not an implemented or clinically verified pipeline. Choose exact dependencies after a reproducible, licensed sample case is available.

What The Next Demo Should Show

A 3-minute evidence-backed demonstration

- 1. Open a licensed thoracic case with its original scan and source attribution.
- 2. Scroll the CT volume and show the same location in the 3D scene.
- 3. Toggle reviewed lungs/lobes, airway, vessels and a reader-marked nodule where available.
- 4. Inspect the nodule's spatial relationships; identify unreviewed or missing labels.
- 5. Add a case-discussion annotation and export a report with provenance and limitations.

Build first	Keep out of the first demo
Side-by-side CT and full-size 3D anatomy; axial/coronal/sagittal review; deterministic camera presets.	Generative image enhancement presented as recovered anatomy.
Structure controls, cut planes, reviewed label overlay, legend, reversible edits and explicit units.	Auto-selected resection planes, guaranteed margins or automated treatment recommendations.
Case provenance, reviewer state, original/edited comparison and an export that reproduces the session.	Unvalidated success percentages, mortality, predicted blood loss or fabricated AI confidence.
Optional VR exploration after desktop geometry is verified; desktop fallback remains fully usable.	Tracked intraoperative navigation, tissue-cutting physics, surgical haptics or invented cardiac motion.

Demo release checks (engineering proposals)

Check slice ordering and laterality using a known reference. Confirm overlays and models align in all three planes. Verify physical measurements against the source tool using clinician-agreed tolerances. Test desktop/mobile framing, nonblank canvas, controls, exports and missing-data states. No public-demo asset should contain patient identifiers.

Honest presentation language

'This is an educational prototype using a licensed de-identified CT case. The structures are annotated or reviewer-approved as shown. The system is not clinically validated and is not for patient-care decisions.'

Validation Before Clinical Claims

IMDRF good machine learning practice emphasizes data representative of the intended population, independent testing, suitable reference standards, human-AI interaction and lifecycle monitoring. These principles support study design; they are not an authorization. [23]

Gate	Design proposal	Evidence to retain
A. Geometry	Synthetic/known-geometry tests plus real scan checks; include anisotropic, oblique and incomplete series.	Ordering, affine and units tests; measured errors; deterministic reconstruction; transform round-trip results.
B. Anatomy	Two qualified reviewers with adjudication where feasible; independent external cases not used in development.	Per-structure Dice and surface-distance measures plus missed/false branches, topology, error severity and correction time.
C. Reader study	Randomized/counterbalanced CT-only, desktop 3D and VR tasks; same underlying data; reduce repeat-case learning.	Objective anatomy identification, review time, critical mistakes, usability, discomfort and retention for educational claims.
D. Clinical study	Only after approvals and suitable authorization: prospective procedure-specific comparator; registered protocol and statistician.	Prespecified primary endpoint; adverse events; relevant margins/outcomes; follow-up, missing-data plan and confidence intervals.

Do not use a single accuracy score

A high overlap score can hide a missed small vessel or a left/right mistake. Evaluate structures and clinical failure modes separately. Do not display model probabilities as calibrated confidence unless calibration has been assessed. Record every exclusion and failed inference, not only successful cases.

Numbers are protocol decisions

Sample size and acceptance thresholds require the intended task, risk level, expected effect, variability and expert agreement. This report does not invent a universal Dice target, '99% accuracy' threshold or patient-study sample size. Use external-site and patient-level splits; scan duplicates and pretrained-model overlap can otherwise contaminate testing.

Stop rule

Any unresolved critical anatomical error, incorrect spatial scale, undisclosed provenance or forbidden data use blocks a clinical-facing release. Failed cases remain in the study accounting.

Global Regulatory Comparison

Market	Verified framework / boundary	Startup action
United States [19] [24]	FDA's Jan 2026 CDS guidance distinguishes non-device CDS from device functions; medical-image processing fails the image criterion. QMSR took effect 2 Feb 2026, incorporating ISO 13485:2016.	Assume patient-specific surgical planning needs a formal device assessment. Discuss scope/predicate suitability and evidence with an RA specialist/FDA; do not declare an exemption because a surgeon reviews outputs.
European Union [20] [33]	MDR software qualification and Rule 11 depend on intended purpose and potential harm. Decision software starts at IIa under that rule, with higher-risk exceptions. AI Act interaction also needs assessment.	Document purpose and risks; assess all applicable rules with regulatory expertise/notified body. Build technical and clinical evidence. Verify AI obligations and current application dates before launch.
United Kingdom [21]	Great Britain uses UK MDR 2002 (as amended); Northern Ireland follows EU device rules. MHRA registration, conformity routes and representation requirements are distinct.	Scope GB and NI separately. A non-UK manufacturer needs a UK Responsible Person for GB; confirm applicable CE/UKCA transition and post-market requirements.
India [22]	CDSCO's 2026 MDSW guidance under MDR 2017 addresses software purpose, classification, submissions and evidence. Its purpose elements expressly include anatomy measurement, segmentation and reconstruction.	Map the exact software function against MDR rules and current classification lists. Confirm licensing authority, research/test permissions and clinical-investigation requirements before any patient-care pilot.

No blanket global clearance

Comparable FDA-cleared products exist, but they do not determine SURGIVISION's class or guarantee a 510(k). Conformity, investigation permissions, privacy and institutional approval are separate questions. Professional regulatory advice is needed before medical use.

Other markets, including Canada, Australia, Japan and China, need separate assessments. This is a four-market comparison, not worldwide legal clearance. Guidance dates above were checked on 11 October 2026; re-check at each development and launch gate.

Competition And Differentiation

Product / source	Verified or vendor-described scope	Implication for SURGIVISION
Ceevra [26] [27] [28]	Thoracic segment models, anatomy toggles and margin simulation. Vendor describes annual volume-tier subscriptions and AI plus imaging technologists. FDA summary K233568 covers Reveal 3+.	A mature scan-to-model service is direct competition. Compare actual preparation/review effort and procurement terms, not just visual features.
Materialise [29] [30]	FDA records: Mimics Thoracic Planner K251964 cleared 12 Mar 2026; Mimics Cardiac Planner K233217 cleared 12 Feb 2024.	Both heart and lung planning are established product categories. Clearance is product/indication-specific, not validation of every vendor feature.
Surgical Reality / PulmoVR lineage [31] [02]	Current surgical-visualization company; PulmoVR clinical publications demonstrate a dedicated lung workflow.	VR-specific anatomy review is not an untouched niche. Current version/geography-specific authorization requires further diligence.
Thirona LungQ [32]	Vendor describes lung anatomy, quantitative CT capabilities and OEM integration; use and availability vary by geography.	Potential technology partner or competitor. Determine whether building every segmentation module creates real value.
3D Slicer [17]	Commercially usable open-source research platform; not an FDA-approved product.	An important build/buy baseline. Paid value must exceed free research software through workflow, support or verified performance.

Differentiation hypotheses to test

Faster reviewer-approved case preparation; explicit scan-to-model provenance; desktop-first team review with optional VR; local/on-prem deployment where required; predictable operating cost and training support. These are hypotheses, not proven advantages or uniquely owned features.

Commercial diligence still needed

Obtain written quotes and version-specific indications. Compare turnaround, scan requirements, manual work, export rights, security review, integration costs and support. Conduct a freedom-to-operate review before copying planning tools; public papers do not grant patent rights.

A Business Model That Can Be Tested

First customers and decision makers

Start discovery with thoracic teaching programs and simulation centers for an educational product. For a future clinical track, target procedure-specific surgical teams with radiology and hospital IT/security involved from the start. Users, budget owners, procurement and data controllers may be different people.

Question	Evidence needed before a business claim
Who pays?	Budget-owning interview; present workflow; procurement requirements; acceptable educational versus clinical use.
What problem is expensive?	Observe case preparation and review; measure reviewer minutes, rework, delivery delays and training effort.
What is the differentiation?	Same cases and tasks compared against current CT workflow, desktop 3D and existing vendors.
What price is viable?	Written quotes, paid pilot proposals and customer-specific willingness to pay. No verified SURGIVISION selling price exists.

Proposed packaging

Education: institution subscription, reviewed case library, desktop access and optional headset support. Clinical later: scoped annual subscription or per-case service after authorization, with reviewer effort and liability included. Competitor Ceevra publishes an annual volume-tier model; that does not determine our price. [27]

Bottom-up economics, not invented market numbers

Serviceable revenue = eligible institutions x adoption assumption x annual contract value. Per-case contribution = realized revenue - reviewer labor - compute/storage - support - licensed technology costs. Annual contribution then deducts quality, security, regulatory and product-development costs.

Count eligible institutions and procedures locally, not total global cancer cases. Maintain separate countries/currencies and conservative adoption assumptions. Do not claim hospital savings until a study measures resource use, and do not assume that reducing one operative phase frees an entire operating-room slot.

Recommended discovery target

Interview a balanced initial group of surgeons, imaging reviewers, trainees, IT/security staff and budget owners across more than one market. This is a proposed work package, not evidence of demand or a commitment from any institution.

Roadmap, Risks And Remaining Gaps

Stage	Deliverable	Go / no-go gate
Days 1-15	One procedure scope; specialist advisors; data-rights register; intended-use draft; customer discovery.	Permission to use selected data; clinical and regulatory owners agree on scope.
Days 16-30	A few traceable retrospective/public CT cases, reviewed masks, linked slices and 3D display.	Geometry, laterality and privacy checks pass; no unsupported anatomy.
Days 31-60	Reviewer workflow, reproducible exports, failure logging and desktop/VR usability pilot.	Clinician-approved error handling and tolerances; revision effort recorded.
Days 61-90	Pilot protocol, external-test plan, cost model and scoped regulatory strategy.	Evidence supports the next investment. Clinical trials/authorization are not promised within 90 days.

Privacy, security and rights

HHS distinguishes Expert Determination and Safe Harbor de-identification; removing a patient's name alone does not establish either. DICOM confidentiality options address identifying pixel annotations and require actual pixel removal rather than a concealing overlay. [\[25\]](#) [\[18\]](#)

Proposed controls: approved institutional data transfer, least-privilege access, encryption, audit logs, retention/deletion rules, redaction QA and no patient scans sent to general AI services. Assess applicable data-protection law, contracts, cross-border transfer and breach duties with counsel in each launch market. Public dataset permission and hospital authorization are separate.

Unresolved questions that matter

Which precise procedure and users? Who will review anatomy? Which data are fit for that use? What external validation access exists? What exact device class/path applies? What will hospitals pay? What licensed technology, patents and brand-name conflicts exist? What budget and team can sustain quality and support?

Investor-ready description (proposed)

'SURGIVISION AI is developing a traceable cardiothoracic anatomy-review platform, starting with thoracic CT case review and training. Our next milestones are licensed case acquisition, specialist-reviewed reconstructions, a comparative usability study and a procedure-specific regulatory plan.'

This roadmap is an estimate dependent on expertise, resources and data access. It does not assert clinical efficacy, a regulatory approval date, a validated AI model, or a funded/contracted pilot.

Source Register

Accessed 11 October 2026. Click a title to open its source. Full URLs, provenance and limitations are also in the companion JSON register.

[01] WHO: Lung cancer

WHO | Official fact sheet; 16 April 2026

[02] Sadeghi et al.: VR and AI for planning lung segmentectomies

JTCVS Techniques / PubMed | 2021; prospective pilot; abstract reviewed

[03] Bakhuis et al.: Plan modifications in 50 segmentectomies

Annals of Thoracic Surgery / PubMed | 2023 issue; online 6 September 2022; abstract reviewed

[04] Chen et al.: DRIVATS randomized controlled trial

European Journal of Cardio-Thoracic Surgery / PubMed | 1 July 2024; multicentre RCT; abstract reviewed

[05] Liao et al.: Patient-specific 3D reconstruction randomized trial

Frontiers in Oncology / PubMed | 21 August 2026; RCT; abstract reviewed

[06] Sadeghi et al.: Immersive VR in adult cardiac surgery

European Heart Journal - Digital Health / PubMed | 23 November 2020; early experience; abstract reviewed

[07] Kanschik et al.: VR in TAVI randomized trial

Circulation: Cardiovascular Imaging / PubMed | 22 April 2026; online ahead of print; abstract reviewed

[08] Patel et al.: Stereoscopic VR and congenital-heart knowledge

International Journal of Cardiovascular Imaging / PubMed | July 2021; randomized educational trial; abstract reviewed

[09] International Delphi consensus on minimally invasive segmentectomy

European Journal of Cardio-Thoracic Surgery | 2024; primary expert-consensus report; results reviewed

[10] LIDC-IDRI

The Cancer Imaging Archive | Collection record; indexed download/license table reviewed

[11] TotalSegmentator CT dataset v3.0.0

University Hospital Basel / Zenodo | 10 September 2026; version-pinned record

[12] TotalSegmentator v3 official license metadata

Zenodo record API | Official API metadata retrieved on 11 October 2026

Source Register

Accessed 11 October 2026. Click a title to open its source. Full URLs, provenance and limitations are also in the companion JSON register.

[13] [ASOCA coronary-artery challenge](#)

ASOCA organizers / Grand Challenge | Challenge-owner description; access links reviewed

[14] [TotalSegmentator official repository](#)

University Hospital Basel / project maintainers | Live README reviewed; pin a release before implementation

[15] [DICOM PS3.3: Image Plane Module](#)

DICOM Standards Committee / NEMA | Current page identified as 2026d when reviewed

[16] [3D Slicer: Image segmentation](#)

3D Slicer maintainers | Latest documentation reviewed

[17] [3D Slicer commercial use](#)

3D Slicer project | Official project statement reviewed

[18] [DICOM PS3.15: Confidentiality options](#)

DICOM Standards Committee / NEMA | Current confidentiality-options page reviewed

[19] [FDA: Clinical Decision Support Software](#)

US FDA | Final guidance issued 29 January 2026

[20] [MDCG 2019-11 revision 1: Software qualification/classification](#)

Medical Device Coordination Group | June 2025; guidance, not binding law

[21] [MHRA: Regulating medical devices in the UK](#)

UK MHRA | Updated 20 February 2026

[22] [CDSCO: Medical Device Software under MDR 2017](#)

CDSCO, Government of India | Official index lists release 21 July 2026; final guidance

[23] [IMDRF: Good machine learning practice](#)

International Medical Device Regulators Forum | N88 FINAL:2025; 29 January 2025

[24] [FDA: Quality Management System Regulation](#)

US FDA | Effective 2 February 2026

Source Register

Accessed 11 October 2026. Click a title to open its source. Full URLs, provenance and limitations are also in the companion JSON register.

[25] HHS: De-identification guidance

US HHS Office for Civil Rights | Official HIPAA guidance reviewed

[26] Ceevra for thoracic surgery

Ceevra | Current official product description reviewed

[27] Ceevra: How it works

Ceevra | Current official workflow/pricing-model description reviewed

[28] FDA: Ceevra Reveal 3+ 510(k) summary

US FDA | K233568; scope and comparison table reviewed

[29] FDA: Mimics Thoracic Planner

US FDA | K251964; decision 12 March 2026

[30] FDA: Mimics Cardiac Planner

US FDA | K233217; decision 12 February 2024

[31] Surgical Reality

Surgical Reality | Current official website reviewed

[32] Thirona: Pulmonary interventions

Thirona | Current official product description reviewed

[33] MDCG 2025-6: MDR/IVDR and AI Act interplay

AI Board / Medical Device Coordination Group | June 2025; nonbinding FAQ

[34] Creative Commons Attribution 4.0

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Research provenance and limits

Searches prioritized official regulators, original studies indexed in PubMed, dataset owners, standards maintainers and first-party product records. Failed full-page fetches and abstract-only appraisals are disclosed in the register. No proprietary clinical data, restricted-account content or paid market estimates were used.

Retrieval emphasized cardiothoracic anatomy review, segmentectomy and cardiac planning. This brief does not exhaust all cardiothoracic indications or substitute for a formal systematic review. Independent medical, legal and regulatory review is required before using this material to support patient care or marketing claims.