

The 2026 Surgical Technology Intelligence Report

What changed, who matters, what actually reached the operating room, and what to watch next.

CONTENTS

Inside this report

Executive summary 3

How to read this report 4

Chapter 1: A Year of Regulatory Milestones 6

Chapter 2: The Shifts That Mattered 9

Chapter 3: The Companies That Matter 11

Chapter 4: What Actually Reached the Operating Room 14

Chapter 5: The Clinical Evidence Worth Knowing 17

Chapter 6: What to Watch Next 20

Appendix A: Dated milestones 22

Appendix B: Systems covered 23

Appendix C: Source index 24

EXECUTIVE SUMMARY

The year in one page

Between July 2025 and October 10, 2026, surgical robotics moved from one dominant platform toward a multi-vendor market, while autonomy stayed mostly in the laboratory.

- 1. The market opened, and the funding test got harder.** Hugo was cleared for urology on December 3, 2025, and Ottava received De Novo authorization on July 22, 2026, while Vicarious Surgical's stockholders approved an asset transfer to creditors on July 21, 2026.
- 2. The first rulebook assumes a surgeon at the console.** The FDA's draft guidance of September 25, 2026 covers teleoperated systems and excludes robots that perform significant aspects of a procedure independently.
- 3. Autonomy advanced in the lab and in narrow tasks.** SRT-H completed a multi-step portion of cholecystectomy on ex vivo tissue, ARISE succeeded in animal eyes, and the only cleared autonomous task in the verified database is a blood draw.
- 4. AI reached the operating room as software that helps surgeons see, plan, and navigate.** Of 97 surgical authorizations on the FDA's AI-enabled device list in this analysis, 8 are robotics.
- 5. The evidence behind new clearances is small and often company-stated.** Several recent clearances rest on studies of about 30 patients, and every company-reported figure in this report is labeled.
- 6. The calendar to watch is dated.** Comments on the FDA's generative AI paper are due October 19, 2026, Hugo's general surgery and gynecology 510(k)s are pending, and the surgical robotics draft guidance is open for comment.

WHAT THIS MEANS FOR SURGEONS

Read the indication list before the brand name, because each clearance covers named procedures.

Treat company-reported figures as claims until a peer-reviewed study or regulatory record supports them.

Judge any autonomy claim by its testing stage: ex vivo, animal, human, or cleared use.

CHAPTER 2

The Shifts That Mattered

ANALYSIS · WHAT CHANGED, NOT WHAT HAPPENED

A list of clearances shows what happened, but it does not show what changed.

This chapter separates the events that moved the field from the events that only filled the news cycle.

Each shift is anchored to a dated record.

Autonomy Moved From Single Tasks to Multi-Step Work

In July 2025, Johns Hopkins researchers reported SRT-H, a system that autonomously completed a multi-step portion of a cholecystectomy.

It succeeded on eight unseen ex vivo porcine gallbladders without human intervention.

The system learned from about 17 hours of data, covering 16,000 trajectories across 34 gallbladders.

Earlier autonomous demonstrations centered on single tasks such as suturing, so a multi-step sequence is a genuine advance.

The tissue was ex vivo, so there was no live patient and no living physiology to manage.

Source: [Kim et al., SRT-H \(Johns Hopkins\), Science Robotics, preprint](#)

Autonomy Arrived First Where the Task Is Narrow

In January 2026, the Institute of Automation at the Chinese Academy of Sciences published ARISE in Science Robotics, a system for autonomous retinal injections.

The authors reported 100% success across eyeball phantoms, ex vivo porcine eyes, and in vivo animal eyes.

They also reported positioning errors about 80% lower than manual surgery and about 55% lower than surgeon-controlled robotic surgery.

Aletta, authorized on August 19, 2026, is the only cleared autonomous task in the verified database, and that task is a blood draw.

Across these three systems, the narrower the task, the closer the system sits to patients.

That pattern is an analytical reading of the records, not a finding any of them reports.

Source: [FDA, Aletta announcement](#); Science Robotics, Institute of Automation, Chinese Academy of Sciences (January 2026)

Authorization and Survival Became Separate Tests

On July 21, 2026, stockholders of Vicarious Surgical approved transferring substantially all of the company's assets through an assignment for the benefit of creditors.

Ottava received its De Novo authorization the next day, on July 22, 2026.

Regulatory authorization and financial survival are different hurdles, and the field produced both outcomes on consecutive days.

For a hospital, the financial footing of a vendor is part of the risk of adopting a new platform.

Source: [SEC, Vicarious Surgical Form 8-K, July 21, 2026](#)

The Rulebook Assumes a Surgeon at the Console

The draft guidance of September 25, 2026 covers teleoperated systems used under direct control or supervision of a practitioner.

Autonomous robots that perform significant aspects of a procedure independent of the practitioner fall outside it.

AI and machine learning features are addressed through early discussion with the FDA and through Predetermined Change Control Plans.

Manufacturers of systems outside the scope are directed to individual feedback through the Q-Submission Program.

Source: [FDA, Robotically-Assisted Surgical Devices Premarket Submissions \(draft guidance\)](#)

WHAT THIS MEANS FOR SURGEONS

Autonomy claims should be read by testing stage, because ex vivo, animal, human, and cleared use are four different levels of evidence.

The records in this chapter suggest that systems automating one narrow task will reach practice before systems automating whole procedures.

A new platform's clearance should be weighed alongside the financial footing of its maker.

Read the full report.

You have read the executive summary and one chapter of the 26-page edition. The full report adds:

- A Year of Regulatory Milestones
- The Companies That Matter
- What Actually Reached the Operating Room
- The Clinical Evidence Worth Knowing
- What to Watch Next
- Dated milestones, systems covered, and a linked source index

Get the full report, \$39

nextinsurgery.gumroad.com/l/wevyzv