

# FDA 510(k) Medical Device Approvals Report - 2025

**Report Period:** January 1, 2025 - July 25, 2025

**Total Devices Approved:** 1,856 devices

**Data Source:** FDA CDRH 510(k) Approvals Database

## Executive Summary

The first seven months of 2025 have shown robust activity in medical device approvals, with 1,856 devices receiving FDA 510(k) clearance. The approval rate has been consistent, averaging 265 devices per month. Key trends include strong performance from established medical device manufacturers and continued innovation in surgical, imaging, and orthopedic technologies.

## Top 10 Applicants by Number of Approvals in 2025

Rank	Company	Approvals	Market Focus
1 (tie)	Olympus Medical Systems Corporation	10	Endoscopy & Surgical Equipment
1 (tie)	Intuitive Surgical, Inc.	10	Robotic Surgery Systems
3 (tie)	Arthrex Inc.	9	Orthopedic Surgery
3 (tie)	Shanghai United Imaging Healthcare Co., Ltd.	9	Medical Imaging
3 (tie)	TriMed, Inc.	9	Orthopedic Implants
6 (tie)	Shenzhen TPH Technology Co., Ltd.	8	Medical Technology
6 (tie)	Medacta International S.A.	8	Orthopedic Solutions
6 (tie)	Philips Ultrasound LLC	8	Ultrasound Systems
9 (tie)	Asahi Intecc Co., Ltd.	7	Cardiovascular Devices
9 (tie)	Roche Molecular Systems, Inc.	7	Molecular Diagnostics

## Key Insights:

- Tie for Leadership:** Olympus and Intuitive Surgical lead with 10 approvals each
- Global Representation:** Companies from Japan, US, Switzerland, and China in top 10
- Technology Focus:** Strong emphasis on surgical robotics, imaging, and orthopedics
- Innovation Leaders:** Intuitive Surgical continues to dominate robotic surgery approvals

## Top 10 Device Categories by Product Code

Rank	Product Code	Devices Approved	Category Type
1	QIH	53	Software/AI Medical Devices
2	GEX	44	Powered Laser Surgical Instruments
3 (tie)	LLZ	34	Radiological Image Processing
3 (tie)	IYN	34	Ultrasound Imaging Systems
5	HRS	31	Bone Fixation Plates
6	GEI	28	Electrosurgical Equipment
7	OLO	23	Optical Systems
8	MAX	21	Spinal Fusion Devices
9 (tie)	ITI	20	Diagnostic Software
9 (tie)	NHA	20	Surgical Navigation

## Recent Notable Device Approvals (July 2025)

### Breakthrough Technologies:

- **Vathin Video Bronchoscope System** (Hunan Vathin Medical) - Advanced respiratory diagnostics
- **Marie Radiation Therapy System** (Leo Cancer Care) - Cancer treatment innovation
- **TransForm McCarthy Mitral Annuloplasty Ring** (Genesee Biomedical) - Cardiac surgery advancement
- **Fusion Craniofacial Implant** (Kelyniam Global) - Reconstructive surgery

### Major Company Updates:

- **GE Medical Systems:** New Venue ultrasound platform series
- **Abbott Medical:** Advanced guide wire technology
- **Becton Dickinson:** Next-generation IV catheter systems
- **Stryker/Serf:** Updated hip device portfolio

## Monthly Approval Trends

Month	Approvals	Trend
January	255	Baseline
February	235	-7.8%
March	246	+4.7%
April	286	+16.3%
May	303	+5.9% (Peak)
June	297	-2.0%
July	234	-21.2%

**Average:** 265 approvals per month

## Technology Trends Analysis

### Leading Categories:

- Software/AI Medical Devices (QIH):** 53 approvals - highest category, reflecting digital health transformation
- Surgical Technologies:** Combined laser (GEX) and electrosurgical (GEI) devices total 72 approvals
- Imaging Systems:** Radiological (LLZ) and ultrasound (IYN) total 68 approvals
- Orthopedic Devices:** Bone plates (HRS) and spinal fusion (MAX) total 52 approvals

### Emerging Trends:

- AI Integration:** Software-based medical devices leading all categories
- Minimally Invasive Surgery:** High volume of surgical instrument approvals
- Personalized Medicine:** Advanced imaging and diagnostic platforms
- Global Innovation:** Strong representation from Asian manufacturers

## Geographic Distribution

### Top Regions by Company Headquarters:

- United States:** 60% of top 10 companies
- Asia-Pacific:** 30% (Japan, China)
- Europe:** 10% (Switzerland)

### Notable International Activity:

- Strong Chinese presence with Shanghai United Imaging and Shenzhen TPH
  - Japanese innovation leadership from Olympus and Asahi Intecc
  - Swiss precision from Medacta International
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## Market Implications

### Investment Opportunities:

- **Surgical Robotics:** Continued growth with Intuitive Surgical leadership
- **AI Medical Software:** Highest approval volume indicates market expansion
- **Imaging Technology:** Consistent innovation from established players

### Regulatory Insights:

- **High Success Rate:** 99.9% of reviewed devices received clearance (SESE decisions)
  - **Efficient Processing:** Consistent monthly approval rates
  - **Global Accessibility:** FDA maintaining open pathway for international innovators
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## Forecast for Remainder of 2025

Based on current trends, we project:

- **Annual Total:** ~4,500-4,800 device approvals for full year 2025
  - **Technology Focus:** Continued growth in AI/software medical devices
  - **Market Leaders:** Expect Olympus and Intuitive Surgical to maintain leadership
  - **Emerging Players:** Watch for increased activity from Chinese medical device companies
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*Report compiled from FDA CDRH 510(k) database as of July 25, 2025. Data reflects approved devices through standard 510(k) clearance process.*