

Supplementary Materials

Robotic bedside surgical assistants: a distinct class of surgical robotics

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Supplementary Table 1. Regulatory records of named robotic bedside-assistant systems

Device	Manufacturer/lineage	Bounded supporting task	Execution mode	Regulatory record (pathway, number, date)	Notes
AESOP	Computer Motion	Endoscope (camera) control; voice-controlled	C1	FDA cleared 1994 (first such device for intra-abdominal surgery)	Discontinued after Computer Motion–Intuitive Surgical merger, 2003
EndoAssist/EndoSista	Armstrong Healthcare, later Prosurgics	Endoscope control; head-tracked	C1	CE-marked	Head-tracking lineage; succeeded by FreeHand
FreeHand	Prosurgics/FreeHand 2010 Ltd	Endoscope control; head-tracked	C1	CE-marked; FDA 510(k) K090340 (May 2009)	Successor to the EndoAssist lineage
ViKY	EndoControl	Endoscope/positioner; foot- and voice-driven	C1	FDA 510(k) K082233 (December 2008); CE-marked	Corroborated by manufacturer ClinicalTrials.gov record
SoloAssist/Solo Assist II	AKTORmed	Endoscope (camera) control	C1	CE-marked; FDA 510(k) K171947 (September 2018)	Device in several comparative studies in Table 3
EMARO	Riverfield	Endoscope control; pneumatic, head-tracked	C1	No FDA, CE, or PMDA (Japan) record identified	Reported in clinical use in Japan
FIPS Endoarm; RoboLens; EvoLap	Academic (Karlsruhe/Tübingen; Mirbagheri; Herman)	Endoscope control	C1	No regulatory clearance identified	Research prototypes; never commercialized
AutoLap (with “Follow Me”)	MST; later TransEnterix/Asensus	Instrument-following endoscope control	C2 (interpretively AIONS-consistent)	FDA 510(k) K152848 (FDA decision 17 November 2015)	First clinical experience reported by Wijsman et

					al.; product no longer independently marketed
Maestro (base platform)	Moon Surgical	Endoscope holding/positioning	C1	FDA 510(k) K221410 (cleared 2 December 2022); design-change 510(k) K240598 (cleared 3 June 2024)	Summary states conventional instruments are surgeon-controlled
ScoPilot (Maestro function)	Moon Surgical	Instrument-following endoscope control	C2 (interpretively AIONS-consistent)	FDA 510(k) K242323 (cleared 14 March 2025); subsequent 510(k) K250984 (27 June 2025) with PCCP	Fixed, static instrument-identification model on command
Levita Magnetic Surgical System	Levita Magnetix	Magnetic surgical retraction and positioning (not camera control)	C1	FDA De Novo DEN150007 (2016) for magnetic surgical retraction	Distinct assistance category; kept separate from the MARS record
MARS robotic endoscope-holder arm	Levita Magnetix	Endoscope holding/positioning	C1	FDA 510(k) K223673 (4 August 2023)	Robotic arm configuration; distinct from the De Novo magnetic-retraction record above

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evidence of comparative clinical benefit. FDA: US Food and Drug Administration; 510(k): premarket notification; De Novo: De Novo classification request; CE: Conformité Européenne; PMDA: Pharmaceuticals and Medical Devices Agency (Japan); PCCP: predetermined change control plan; C1: direct surgeon command; C2: delegated rule-based execution.