

March 31, 2020

Intuitive Surgical, Inc Mark Johnson Senior Vice President, Regulatory Affairs 1266 Kifer Road Sunnyvale, California 94086

Re: K183086

Trade/Device Name: da Vinci Xi Surgical System, da Vinci X Surgical System

Regulation Number: 21 CFR 876.1500

Regulation Name: Endoscope and Accessories

Regulatory Class: Class II Product Code: NAY Dated: January 27, 2020 Received: January 28, 2020

Dear Mark Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

K183086 - Mark Johnson Page 2

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice">https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2020 See PRA Statement below.

510(k) Number (if known)

K183086

Device Name

Intuitive Surgical® da Vinci® Xi Endoscopic Instrument Control System (da Vinci Xi System, Model IS4000) and Endoscopic Instruments and Accessories

Indications for Use (Describe)

The Intuitive Surgical Endoscopic Instrument Control System (da Vinci Xi Surgical System Model IS4000) is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps/pick-ups, needle holders, endoscopic retractors, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, and delivery and placement of microwave and cryogenic ablation probes and accessories, during urologic surgical procedures, general laparoscopic surgical procedures, general thoracoscopic surgical procedures and thoracoscopically- assisted cardiotomy procedures. The system can also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. The system is indicated for adult and pediatric use. It is intended to be used by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

Type of Use (Select one or both, as applicable)	
□ Prescription Use (Part 21 CFR 801 Subpart D)	Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2020 See PRA Statement below.

0(k) Number (if known)	
evice Name	
uitive Surgical® da Vinci® X Endoscopic Instrument Control System	
a Vinci X System, Model IS4200) and Endoscopic Instruments and Accessories	
dications for Use (Describe)	

The Intuitive Surgical Endoscopic Instrument Control System (da Vinci X Surgical System Model IS4200) is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps/pick-ups, needle holders, endoscopic retractors, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, and delivery and placement of microwave and cryogenic ablation probes and accessories, during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general thoracoscopic surgical procedures and thoracoscopically- assisted cardiotomy procedures. The system can also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. The system is indicated for adult and pediatric use. It is intended to be used by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

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510(k) Summary (21 CFR § 807.92(c))

I. SUBMITTER INFORMATION

Submitter: Intuitive Surgical, Inc.

1266 Kifer Road Sunnyvale, CA 94086

Contact: Mark Johnson

Senior Vice President, Regulatory Affairs & Program Management Office

Intuitive Surgical, Inc. Telephone: 650-523-8027

Email: Mark.Johnson@intusurg.com

Date Summary Prepared: March 24, 2020

II. SUBJECT DEVICE INFORMATION

Device Trade Name: da Vinci® Xi and X Surgical Systems, Model IS4000 and Model IS4200

Common Name: System, Surgical, Computer Controlled Instrument **Classification Name:** Endoscope and Accessories (21 CFR §876.1500)

Regulatory Class: II
Product Code: NAY

Submission Type: Traditional 510(k)

III. PREDICATE DEVICE INFORMATION:

Predicate Devices: Intuitive Surgical da Vinci Xi and X Surgical Systems, Models IS4000 and

IS4200 (K131861, K152578, K153276, K161178, K170713, K171632, K171294

K172643, K173842, K173585 and K182140)

Intuitive Surgical da Vinci Si Surgical System, Model IS3000 (K081137,

K123463, K090993)

IV. DEVICE DESCRIPTION:

This 510(k) is for a labeling modification only, to include the following additional representative, specific procedure under the cleared "general laparoscopic surgical procedures" and "general thoracoscopic surgical procedures and thoracoscopically-assisted cardiotomy procedures" Indications for Use of the *da Vinci Xi* Surgical System, Model IS4000 (K131861) and the *da Vinci X* Surgical System, Model IS4200 (K171294) and the associated labeling claims: Esophagectomy. There are no changes to the technological characteristics of the cleared *da Vinci Xi or X* Surgical Systems (Models IS4000 and IS4200) proposed in this submission. The *da Vinci Xi and X* Surgical Systems, Models IS4000 and IS4200, are software-controlled, electro-mechanical systems designed for surgeons to perform minimally invasive surgery. The Model IS4000 and Model IS4200 Surgical Systems consist of a Surgeon Console, a Patient Side Cart (PSC), and a Vision Side Cart (VSC) and are used with an Endoscope, *EndoWrist* Instruments, and Accessories.

V. INDICATIONS FOR USE

The Intuitive Surgical Endoscopic Instrument Control System (*da Vinci* Surgical System, Models: IS4000 and IS4200) is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps/pick-ups, needle holders, endoscopic retractors, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, and delivery and placement of microwave and cryogenic ablation probes and accessories, during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general thoracoscopic surgical procedures and thoracoscopically-assisted cardiotomy procedures. The system can also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. The system is indicated for adult and pediatric use. It is intended to be used by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

Precaution for Representative Uses

The demonstration of safety and effectiveness for the representative specific procedures did not include evaluation of outcomes related to the treatment of cancer (overall survival, disease-free survival, local recurrence) or treatment of the patient's underlying disease/condition. Device usage in all surgical procedures should be guided by the clinical judgment of an adequately trained surgeon.

VI. COMPARISON OF INTENDED USE, INDICATIONS FOR USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

There are no changes to the technological characteristics for the subject devices compared to the cleared predicate devices, *da Vinci Xi* Surgical System, Model IS4000 (K131861) and the *da Vinci X* Surgical System, Model IS4200 (K171294). This 510(k) is for a labeling modification to include Esophagectomy as a labeled use under the cleared "general laparoscopic surgical procedures" and "general thoracoscopic surgical procedures and thoracoscopically-assisted cardiotomy procedures" Indications for Use of the cleared predicate devices, *da Vinci Xi* Surgical System, Model IS4000 and the *da Vinci X* Surgical System, Model IS4200. The subject devices differ from the predicate devices by this modification to the labeling. Results of clinical data from literature demonstrated that the subject devices have the same intended use as the predicate devices.

VII. PERFORMANCE DATA

There were no technological changes to the subject devices, thus no bench testing, electromagnetic compatibility testing, sterilization testing or biocompatibility testing was required.

Clinical Study Data

Published clinical data were provided to support use of the *da Vinci Xi and X* Surgical Systems (Models IS4000 and IS4200) in "Esophagectomy" procedures to demonstrate that the intended use of the devices is the same as the predicate devices. Seventeen (17) publications were identified for this procedure based on specific search criteria and filters used in three (3) search engines: PubMed, Scopus and Embase and two (2) separate searches. The search terms, inclusion/exclusion criteria and the flowcharts depicting the results from these searches are provided in **Figures A** and **B**. These publications included: one (1) prospective study (LOE 2b); five (5) database studies (LOE 2b/2c) and eleven (11) retrospective studies (LOE 3b) comparing *da Vinci*-assisted procedures with minimally invasive, laparoscopic and/or video-assisted cohorts. A detailed summary of the published clinical data on this procedure is provided in **Tables 1A** and **1B** below.

The findings from the Esophagectomy publications demonstrate that *da Vinci*-assisted procedures as compared to minimally invasive, laparoscopic and/or video-assisted procedures are found to be substantially equivalent based on the following endpoints:

- Mortality Rates
- Estimated Blood Loss (EBL) Volumes
- Blood Transfusion Rates
- Lengths of Hospital Stay (LOS)
- Intraoperative Complication Rates
- Postoperative Complication Rates
- Conversion Rates
- Reoperation Rates
- Readmission Rates
- Anastomotic Leak Rates
- Operative Times

Anastomotic Leak Rate Subgroup Analysis

In the *da Vinci*-assisted group, the handsewn sutured cohort had an ALR of 14.73% and the stapled cohort had an ALR of 9.24% (difference of 5.49%). In the MIE group, the handsewn sutured cohort had an ALR of 8.72% and the stapled cohort had an ALR of 9.86% (difference 1.14%). Importantly, the vast majority of the sutured anastomoses for both cohorts were performed in an open manner in the neck. Although the handsewn sutures cohort of the da Vinci group (14.73%) had the highest leak rates amongst the 4 groups compared, this number still appears to be within the reported range (roughly 5-15%) for ALR for esophagectomy procedures. While taking into consideration these published data showing potentially less risk of anastomotic leak with a stapled anastomosis during robotic-assisted esophagectomy, ultimately the appropriate location and technique for the anastomosis should be based on clinical assessment of patient factors as well as the experience and training of the surgeon.

Learning Curve Publications

A total of 17 publications that evaluated the learning curve associated with *da Vinci*-assisted esophagectomy procedures across different surgeons with varying levels of clinical and surgical expertise were also evaluated. These published reports identified a learning curve of 3 - 80 cases

associated with *da Vinci*-assisted esophagectomy procedures. This information is reflected in the following statement included in the device labeling:

"The da Vinci Xi or X Surgical System should only be used in esophagectomy procedures performed by experienced foregut and/or thoracic surgeons who have credentials and privileges to perform such procedures at their institution. Additionally, Intuitive recommends experience with the da Vinci Xi or X Surgical Systems in less complex procedures (e.g., thymectomy, Nissen Fundoplication) prior to use of the system in esophagectomy procedures. Published literature indicates that the learning curve associated with stabilization of operative time of da Vinciassisted esophagectomy procedures can range from 3-80 cases. Intuitive encourages the use of a proctor or preceptor during use of the device in early esophagectomy procedures."

VIII. CONCLUSION

The *da Vinci Xi* and *X* Surgical Systems (models IS4000 and IS4200) have the same intended use as the predicate devices, as demonstrated by the clinical data from the literature to support the safety and effectiveness for the new labeled use of Esophagectomy procedures under the "general laparoscopic surgical procedure" and "general thoracoscopic surgical procedures and thoracoscopically-assisted cardiotomy procedures" indications as compared to the predicate devices. In addition, the subject devices have the same technological characteristics as the predicate devices. Therefore, the *da Vinci Xi* and *X* Surgical Systems (Models IS4000 and IS4200) are substantially equivalent to the cleared predicate devices.

TABLE 1A: da Vinci vs. Minimally Invasive/Laparoscopic/Video-Assisted Esophagectomy ("MIE") Procedures

Author/Year	Study Size (N)	(N)	Operation	EBL (ml)	Length of	Transfusion	Intraop	Postop	Mortality	Reoperation	Readmission	Conversion
			Time (minutes)		Stay (days)	Rate (%)	Comp Rate (%)	Comp Rate (%)	(in-hospital - 30 days, %)	Rate (%)	Rate (%)	Rate (%)
1. Weksler 2017*	Robotic	269			1014	(+			5.6	Not	7.0	Not
	MIE	269			Not Reported	or red			2.8	Reported	6.5	Reported
2. Yerokun 2016*	Robotic	170	100 + 0 N	0,120	10^		10 + ON		3.7	Not	5.9	Not
	MIE	170	ואסר הפן	Joi ted	10^		ואסר הפשטו נפת		2.7	Reported	8.8	Reported
3. Diez del Val 2015	Robotic	34	+014		17.4	°0 +°14	- t	41.18	8.8	2.9	Not	8.8
	MIE	17	Not Reported	oor ted	25.9	NOT KE	Not Reported	64.71	17.6	17.6	Reported	11.8
4. Suda 2012	Robotic	16	692.5^	144.5	22		10 + ON		0		to the contract of the contrac	
	MIE	20	649.5^	139	35.5		Not Reported		0		nor reported	
5. Chao 2018	Robotic	39	149.33	83.33	16.36	15.4	Not	20.5	0^^	12.8	10.3	0
	MIE	29	156.05	120.75	17.82	0.6	Reported	34.3	4.5	14.9	16.9	0
6. Park 2016	Robotic	62	490.3 ± 84.0	462.9 ± 493.9	Not		L 042000 C 4014		1.6	7G + 7N	1	1.6
	MIE	43	458.4 ± 111.9	466.8 ± 333.0	Reported		Not Reported		0	NOT KE	Not Reported	2.3
7. Weksler 2012	Robotic	11	439±70	200±150	8.7 ± 3.4	Not	0	36.4	0.0	1	4	0
	MIE	26	483.8 ± 76.5	226±372	10.0 ± 7.7	Reported	0	38.5	7.7	NOT KE	Not Reported	3.85
8. Deng 2018	Robotic	79	353	96.3	14.3	0	Not	28.8**	3.8^^	2	1	0
	MIE	72	274	127.5	12.7	0	Reported	23.1**	3.8^^	NOT KE	Not Reported	0
9. He 2018	Robotic	27	349 ± 45	119±72	13.8 ± 2.0	-0 +-14	1	*v / E	0		1	
	MIE	27	285 ± 66	158 ± 82	12.8 ± 2.7	NOT KE	Not Keported	33.3^*	3.7		иот керогтеа	
10. Motoyama 2019	Robotic	21	634.0	492	Not				40 to 10			
	MIE	38	598.5	385	Reported				Not Reported			
11. Zhang 2019	Robotic	9/	303.5	200	9.0	÷ 1	4	31.6^*	0	~ C + ~ I v		2.6
	MIE	108	277.2	200	9.0	ווסון אפ	Not Reported	33.3^*	0	ווסון אפן	Not Reported	0
12. Tagkalos 2019	Robotic	20	388	339	12.0		20 40 N		5.0^^		+ 0 14	
	MIE	20	321	343	12.5		ואסו עבלאטונבת		2.5^^		ואסר עבליסו ובת	
13. Harbison 2019	Robotic	100	445	L C + C I V	10	10.0	Not	31.0^*	3.0	17.0	18.0	11.0
	MIE	625	418	Not Reported	12	9.76	Reported	39.2^*	2.2	16.3	11.7	8.48
14. Meredith 2019	Robotic	144	409	155	6	1	1	23.6	1.4	1	-	0
	MIE1	158	231-299	189-242	9-10	Not ke	Not Reported	29.5-49.2	2.1-3.2	NOT Ke	Not Keported	7.4-12.7
15. Washington 2019	Robotic	18	168		6.6	+014	4	5.6**	0		† *	
	MIE	18	164	Not Reported	8.6	ואטו אפ	Not Reported	11.2**	5.6		nor reported	
16. Chen 2019	Robotic	89	187.2	118.9	17.1		10 to 00 to 10 to		0	0	+017	7
	MIE	74	193.4	116.5	15.2		ואסו הפשטו ופת		0	0	NOL REPOILE	orted
17. Yang 2019	Robotic	271	244.5	210.7	11.0	00+012	70	45.0	0^^	1.5	Not	0.7
	MIE	271	276.0	209.6	11.0	אַר אַר	vot nepot ted	37.3	0.7^^	3.3	Reported	5.9
300000000000000000000000000000000000000	30:0V U** TO	10:10:00		And : A	1-4							

[^]Medians reported, **Major complications, ^* Overall complications, ^^ 90-day mortality rate

^{*}The years 2010, 2011 and 2012 overlap between the two (2) databases used in the Weksler and Yerokun publications. As such, there is a possibility of data overlap in the reported results. $^{1} Publication \ reported \ on \ two \ (2) \ MIE \ cohorts: \ "TL-thoracoscopic/laparoscopic" \ and \ "TH-transhiatal".$

TABLE 1B: da Vinci vs. Minimally Invasive/Laparoscopic/Video-Assisted Esophagectomy ("MIE") Procedures

tric 569 Not Reported 95.1 160 Not tric 170 6.5 93.5 median 16 Not tric 170 4.1 95.9 median 16 Not tric 170 4.1 95.9 median 16 Not tric 17 4.1 95.9 median 16 Not tric 16 10.0 90.9 39.7 37.4 Not tric 6.2 10.0 94.9 2.9 37.3 Not tric 6.2 Not Reported 98 37.3 Not 37.2 Not Not <th>Author/Year</th> <th>Study</th> <th>Study Size (N)</th> <th>Positive Surgical Margin Rate (%)</th> <th>RO Resection Rate (%)</th> <th>Lymph Node Yield (n)</th> <th>Anastomotic Leak Rate (%)</th>	Author/Year	Study	Study Size (N)	Positive Surgical Margin Rate (%)	RO Resection Rate (%)	Lymph Node Yield (n)	Anastomotic Leak Rate (%)
MIE 569 Not Reported 94.6 16.0 Robotic 170 6.5 93.5 median 16 Robotic 34 Not Reported 20.9 30.4 MIE 17 4.1 87.5 37.5 Robotic 39 0 94.9 29 Robotic 39 0 94.9 29 Robotic 39 0 98 37.3 Robotic 11 0 100 23.10 Robotic 20 100 23.10 100 MIE 27 0 100 23.10 Robotic 27 0 100 23.2 Robotic 27 Not Reported 99.1 20.3 MiE 38 Not Reported 99.1 20.3 Mobitic 20 Not Reported 95.2 27 MiE 38 Not Reported 95.2 27 MiE 50 Not Reported <td< th=""><th>1. Weksler 2017*</th><th>Robotic</th><th>269</th><th>7 C C C C C C C C C C C C C C C C C C C</th><th>95.1</th><th>16.0</th><th>1000 G +0N</th></td<>	1. Weksler 2017*	Robotic	269	7 C C C C C C C C C C C C C C C C C C C	95.1	16.0	1000 G +0N
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MIE 67 2.9 88.1 28 Robotic 62 Not Reported 98 37.3 6 MIE 43 Not Reported 100 23 ± 10 6 Robotic 126 0 100 23 ± 10 6 MIE 26 0 100 23 ± 10 6 MIE 72 0 100 23 ± 10 6 Robotic 27 0 100 23 ± 10 6 MIE 27 0 100 23 ± 10 6 MIE 27 0 100 23 ± 10 6 MIE 38 Not Reported Not Reported 100 103 ± 5 8 MIE 50 Not Reported 97.5 23 9 8 MIE 50 6.0 6.0 94.4 14.28 8 9 MIE 138 Not Reported 60-93.5% 9 9 9 MIE	5. Chao 2018	Robotic	39	0	94.9	29	12.8
Mile 62 Not Reported 98 37.3 Perported 98 37.3 Perported 98 37.3 Perported 28.7 Perported 28.7 Perported 28.7 Perported 23.10 Perported 23.10 Perported 23.10 Perported 21.5 Perported 21.5 Perported 21.5 Perported 20.1 Perported 20.2 20.2 20.2 Perported 20.2 Perported 20.2 Perported 20.2 Perported 20.3 Perported		MIE	29	2.9	88.1	28	9.0
MIE 43 Not Reported 98 28.7 Robotic 11 0 100 23 ± 10 MIE 26 0 100 23 ± 10 MIE 72 0 100 1.3.3 MIE 27 Not Reported Not Reported 19 ± 5 MIE 27 Not Reported 59 27 MIE 50 Not Reported 99.1 20.3 MIE 50 Not Reported 95.5 27 MIE 50 Not Reported 60.93.5% 9 MIE 18 Not Reported 60.93.5% 9 MIE 18 Not Reported 60.93.5% 9 MIE 18 Not Reported 94.4 14.28 MIE 18 Not Reported 94.4 13.9 MIE 18 Not Reported 94.4 13.9 MIE 18 Not Reported 94.4 13.9 MIE 74	6. Park 2016	Robotic	62	7 () () () () () () () () () (86	37.3	8.1
MIE 26 10 100 23 ± 10 100 23 ± 10 100 23 ± 10 100 23 ± 10 100 23 ± 10 100 23 ± 10 100 23 ± 10 100 21.5 100 21.5 100 21.5 100 21.5 10.3		MIE	43	ווסר אפססורפת	86	28.7	2.3
MIE 26 0 100 23 ± 10 Patholic 21.5 Patholic 21.5 Patholic 21.5 Patholic 21.5 Patholic 21.5 Patholic 21.5 Patholic 21.3 Patholic 21.3 Patholic 21.3 Patholic 22.4 Patholic 22.4 Patholic 22.4 Patholic 22.4 Patholic 22.4 Patholic 22.4 Patholic 22.2 Patholic 22.2 Patholic 22.3 Patholic 22.3 Patholic 22.3 Patholic 22.3 Patholic 22.2 Patholic 22.4 <	7. Weksler 2012	Robotic	11	0	100	23 ± 10	9.1
AME 79 0 100 21.5 Condition Con		MIE	26	0	100	23 ± 10	15.4
MIE 72 0 100 17.3 Poblit MIE 27 Not Reported Not Reported Not Reported 10± ± 5 Cot ± 7 MIE 23 Not Reported 100 19.7 Poblit 82019 Robotic 50 Not Reported 95.1 20.3 Poblit 82019 Robotic 50 Not Reported 95.2 27 Poblit MIE 50 Not Reported 97.5 23 Poblit Pobli	8. Deng 2018	Robotic	79	0	100	21.5	7.6
MIE 27 Not Reported Not Reported Not Reported 20±7 Not Reported 20±5 Not Reported 20±5 Not Reported 20±5 Not Reported 20±5 S2 Not Reported 19±5 Not Reported 20±7 Not Reported 20±7 Not Reported 20±7 Not Reported 20±7 Not Reported 20±3 Not Reported 20±3 Not Reported 20±3 Not Reported Not Reported 20±3 Not Reported Not Reported 20±3 Not Reported 20±3 Not Reported 20±4 14,28 Not Reported 20±4 14,28 Not Reported 20±3 20±3 Not Reported 20±4 14,28 Not Reported 20±4 14,28 Not Reported 20±4 14,28 Not Reported 20±4 13.9 Not Reported 20±4 20±3 20±3 Not Reported 20±3 20±3 20±3 Not Reported 20±3 20±3 Not Reported 20±3 Not Reported 20±3 Not Reported 20±3 Not Reported 20±3 Not Reported<		MIE	72	0	100	17.3	5.6
MIE 27 Not Reported Not Reported 19±5 19±5 Robotic 21 Not Reported 100 19.7 19.7 MIE 38 Not Reported 99.1 20.3 19.7 MIE 50 Not Reported 97.5 27 100 Robotic 100 6.0 23 100 100 MIE 625 6.7 100 20 100 100 Robotic 144 Not Reported 60-93.5% 9 14.28	9. He 2018	Robotic	27		+0IA	20 ± 7	11.11
Robotic 21 Not Reported 52 59 70		MIE	27	Not kepolted	ואסו עפטסו ופת	19 ± 5	3.70
MIE 38 Not Reported 100 59 Robotic 76 Not Reported 99.1 20.3 MIE 50 Not Reported 95.2 27 MIE 50 Not Reported 97.5 23 Robotic 100 6.0 37.5 23 MIE 158 Not Reported 60-93.5% 9 MIE 18 Not Reported 94.4 14.28 MIE 18 Not Reported 94.4 13.9 MIE 74 Not Reported 100 25.4 MIE 27.1 Not Reported 100 25.4 MIE 27.1 Not Reported 94.1 13.9 MIE 27.1 Not Reported 94.1 20.3 MIE 27.1 Not Reported 93.7 19.2	10. Motoyama 2019	Robotic	21	+ CN	7	52	4.8
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MIE 108 Not Reported 99.1 20.3 Robotic 50 Not Reported 95.5 27 Robotic 100 6.0 7 100 20 MIE 6.5 6.7 100 20 10 Not Reported 60-93.5% 9 14.28 14.28 MIE 18 Not Reported 94.4 14.28 13.9 Robotic 68 Not Reported 100 25.4 13.9 MIE 74 100 25.4 100 25.4 Robotic 271 Not Reported 94.1 20.3 19.2 MIE 271 Not Reported 93.7 19.2 19.2	11. Zhang 2019	Robotic	92	7 () () () () () () () () () (100	19.7	9.2
Robotic 50 Not Reported 95 27 And Reported 97.5 27 And Reported And Reported And Reported And Reported And Reported Mot Reported And Reported Mot Reported And Re		MIE	108	Not Reported	99.1	20.3	5.6
MIE 50 Not Reported 97.5 23 Robotic 100 6.0 Ante to	12. Tagkalos 2019	Robotic	20	7 (1)	95	27	12.0
Robotic 100 6.0 Not Reported Not Reported Not Reported And Reported Not Reported 100 20 20 MIE ¹ 158 Not Reported 94.4 14.28 9 MIE 18 Not Reported 94.4 14.28 8 Robotic 68 Not Reported 100 25.4 8 MIE 74 Not Reported 94.1 20.3 8 Robotic 271 Not Reported 93.7 19.2 19.2 MIE 271 Not Reported 93.7 19.2 19.2		MIE	20	Not Reported	97.5	23	18.0
MIE 625 6.7 Not Reported 60-93.5% 100 20 20 MIE¹ 158 Not Reported 60-93.5% 9 8 MIE 18 Not Reported 94.4 14.28 8 Robotic 68 Not Reported 100 25.4 8 MIE 74 100 24.7 8 Robotic 271 Not Reported 94.1 20.3 MIE 271 Not Reported 93.7 19.2	13. Harbison 2019	Robotic	100	6.0		70 to 00 00 00 to 000	14.0
Robotic 144 Not Reported 100 20 MIE¹ 158 Not Reported 94.4 14.28 Percentage Robotic 68 Not Reported 100 25.4 Percentage Robotic 271 Not Reported 94.1 20.3 Percentage MIE 271 Not Reported 93.7 19.2		MIE	625	6.7	_	vol nepolled	15.4
On 2019 MIE1 158 Not Reported 60-93.5% 9 ANE 18 Not Reported 94.4 14.28 Page 14.28 Robotic 68 Not Reported 100 25.4 Page 14.28 MIE 74 100 25.4 Page 14.2 Robotic 271 Not Reported 94.1 20.3 MIE 271 Not Reported 93.7 19.2	14. Meredith 2019	Robotic	144	7 () () () () () () () () () (100	20	2.8
On 2019 Robotic 18 Not Reported 94.4 14.28 H.28 MIE 18 Not Reported 100 25.4 25.4 MIE 74 100 25.4 24.7 Robotic 271 Not Reported 94.1 20.3 MIE 271 Not Reported 93.7 19.2		MIE ¹	158	Not Reported	60-93.5%	6	5.2
MIE 18 Not Reported 94.4 13.9 Robotic 68 Not Reported 100 25.4 Robotic 271 Not Reported 94.1 20.3 MIE 271 Not Reported 93.7 19.2	15. Washington 2019	Robotic	18	++N	94.4	14.28	5.6
Robotic 68 MIE Not Reported 100 100 25.4 24.7 Control Robotic 271 Not Reported 94.1 20.3 Anil MIE 271 Not Reported 93.7 19.2 Anil		MIE	18	Not nepolted	94.4	13.9	5.6
MIE 74 Not Reported 100 24.7 Robotic 271 Not Reported 94.1 20.3 MIE 271 19.2 19.2	16. Chen 2019	Robotic	89	7 t	100	25.4	8.8
Robotic 271 Not Reported 94.1 20.3 MIE 271 19.2 19.2		MIE	74	near nedering	100	24.7	2.7
271 193.7 19.2	17. Yang 2019	Robotic	271	4+0N	94.1	20.3	11.8
		MIE	271	Not be polited	93.7	19.2	14.4

*The years 2010, 2011 and 2012 overlap between the two (2) databases used in the Weksler and Yerokun publications. As such, there is a possibility of data overlap in the reported results. $^{1} Publication \ reported \ on \ two \ (2) \ MIE \ cohorts: \ "TL-thoracoscopic/laparoscopic" \ and \ "TH-transhiatal".$

FIGURE A: Search Criteria and Flowchart for Literature Search Conducted in January 2019

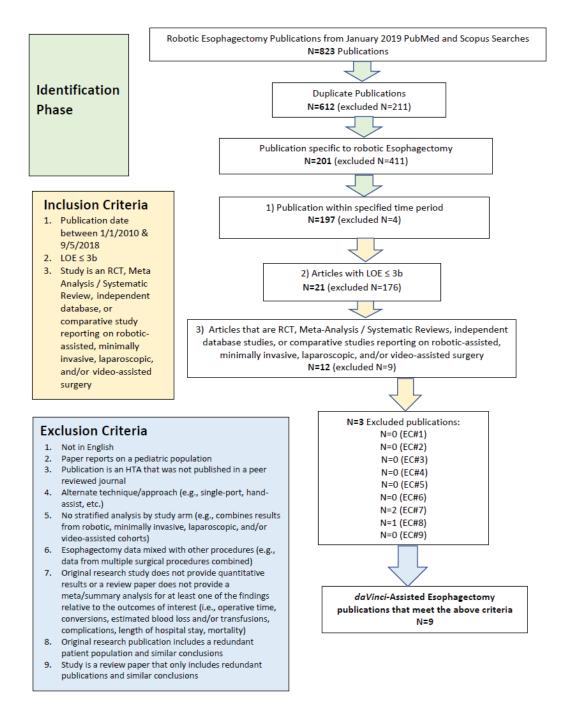


Figure A and the below search terms are associated with the identification of references 1 through 9 listed in Tables 1A and 1B.

PubMed Search Terms: robotic, robot, robot assist, robotically assisted, robot assist, da vinci, davinci, intuitive surgical, robot surgery, esophagectomy, esophageal

Scopus Search Terms: davinci, robotic surgery, intuitive surgical, robotic assist, robot surgery, esophagectomy, esophageal

FIGURE B: Search Criteria and Flowchart for Literature Search Conducted in December 2019

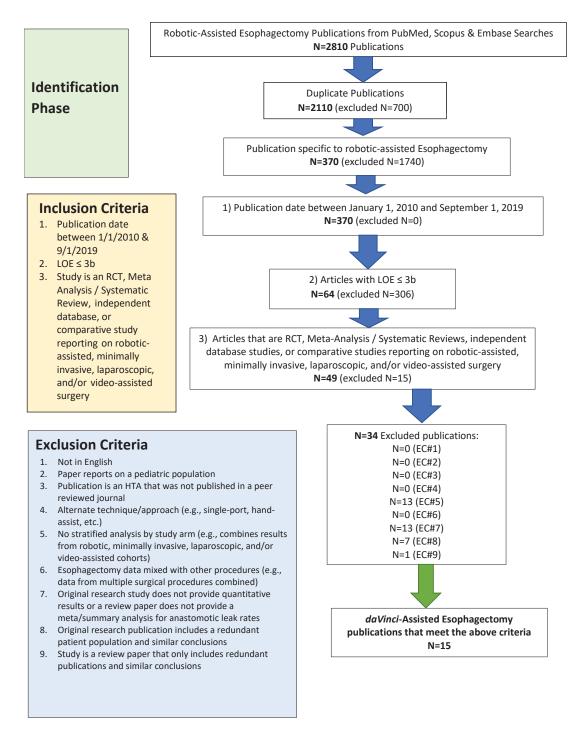


Figure B and the below search terms are associated with the identification of references 3-17 listed in Tables 1A and 1B.

PubMed Search Terms: robotic, robot, robot assist, robotically assisted, robot assist, da vinci, davinci, intuitive surgical, robot surgery, esophagectomy, esophageal, esophagus

Scopus Search Terms: davinci, robotic surgery, intuitive surgical, robotic assist, robot surgery, robotic assist, esophagectomy, esophageal, esophagus Embase Search Terms: da vinci, davinci, intuitive surgical, endowrist, esophagectomy, esophageal, esophagus