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 Federal Register.

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

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-devices/medical-device-safety/medical-device-reporting-mdr-how-report-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) 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, 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.

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.

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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:

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

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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)*

Device Name
Intuitive Surgical® da Vinci® X Endoscopic Instrument Control System
(da Vinci X System, Model IS4200) and Endoscopic Instruments and Accessories

Indications 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.

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)

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K183086

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: lS4000 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

<u>Anastomotic Leak Rate Subgroup Analysis</u>

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.

<u>Learning Curve Publications</u>

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 Vinci-assisted 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)		Operation Time (minutes)	EBL (ml)	Length of Stay (days)	Transfusion Rate (%)	Intraop Comp Rate (%)	Postop Comp Rate (%)	Mortality (in-hospital - 30 days, %)	Reoperation Rate (%)	Readmission Rate (%)	Conversion Rate (%)
1. Weksler 2017*	Robotic	569	Not Reported						5.6	Not Reported	7.0	Not Reported
	MIE	569							2.8		6.5	
2. Yerokun 2016*	Robotic	170	Not Reported		10^	Not Reported			3.7	Not Reported	5.9	Not Reported
	MIE	170			10^				2.7		8.8	
3. Diez del Val 2015	Robotic	34	Not Reported		17.4	Not Reported		41.18	8.8	2.9	Not Reported	8.8
	MIE	17			25.9			64.71	17.6	17.6		11.8
4. Suda 2012	Robotic	16	692.5^	144.5	22	Not Reported			0	Not Reported		
	MIE	20	649.5^	139	35.5				0			
5. Chao 2018	Robotic	39	149.33	83.33	16.36	15.4	Not Reported	20.5	0^^	12.8	10.3	0
	MIE	67	156.05	120.75	17.82	9.0		34.3	4.5^^	14.9	16.9	0
6. Park 2016	Robotic	62	490.3 ± 84.0	462.9 ± 493.9	Not Reported	Not Reported			1.6	Not Reported		1.6
	MIE	43	458.4 ± 111.9	466.8 ± 333.0					0			2.3
7. Weksler 2012	Robotic	11	439 ± 70	200 ± 150	8.7 ± 3.4	Not Reported	0	36.4	0.0	Not Reported		0
	MIE	26	483.8 ± 76.5	226 ± 372	10.0 ± 7.7		0	38.5	7.7			3.85
8. Deng 2018	Robotic	79	353	96.3	14.3	0	Not Reported	28.8**	3.8^^	Not Reported		0
	MIE	72	274	127.5	12.7	0		23.1**	3.8^^			0
9. He 2018	Robotic	27	349 ± 45	119 ± 72	13.8 ± 2.0	Not Reported		37^*	0	Not Reported		
	MIE	27	285 ± 66	158 ± 82	12.8 ± 2.7			33.3^*	3.7			
10. Motoyama 2019	Robotic	21	634.0	492	Not Reported	Not Reported						
	MIE	38	598.5	385								
11. Zhang 2019	Robotic	76	303.5	200	9.0	Not Reported		31.6^*	0	Not Reported		2.6
	MIE	108	277.2	200	9.0			33.3^*	0			0
12. Tagkalos 2019	Robotic	50	388	339	12.0	Not Reported			5.0^^	Not Reported		
	MIE	50	321	343	12.5				2.5^^			
13. Harbison 2019	Robotic	100	445	Not Reported	10	10.0	Not Reported	31.0^*	3.0	17.0	18.0	11.0
	MIE	625	418		12	9.76		39.2^*	2.2	16.3	11.7	8.48
14. Meredith 2019	Robotic	144	409	155	9	Not Reported		23.6	1.4	Not Reported		0
	MIE[1]	158	231-299	189-242	9-10			29.5-49.2	2.1-3.2			7.4-12.7
15. Washington 2019	Robotic	18	168	Not Reported	9.9	Not Reported		5.6**	0	Not Reported		
	MIE	18	164		9.8			11.2**	5.6			
16. Chen 2019	Robotic	68	187.2	118.9	17.1	Not Reported			0	0	Not Reported	
	MIE	74	193.4	116.5	15.2				0	0		
17. Yang 2019	Robotic	271	244.5	210.7	11.0	Not Reported		45.0	0^^	1.5	Not Reported	0.7
	MIE	271	276.0	209.6	11.0			37.3	0.7^^	3.3		5.9

^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

Author/Year	Study Size (N)		Positive Surgical Margin Rate (%)	R0 Resection Rate (%)	Lymph Node Yield (n)	Anastomotic Leak Rate (%)
1. Weksler 2017*	Robotic	569	Not Reported	95.1	16.0	Not Reported
	MIE	569		94.6	16.0	
2. Yerokun 2016*	Robotic	170	6.5	93.5	median 16	Not Reported
	MIE	170	4.1	95.9	median 16	
3. Diez del Val 2015	Robotic	34	Not Reported		20.9	20.6
	MIE	17			24.4	29.4
4. Suda 2012	Robotic	16	12.5	87.5	37.5	37.5
	MIE	20	10.0	90	39	10.0
5. Chao 2018	Robotic	39	0	94.9	29	12.8
	MIE	67	2.9	88.1	28	9.0
6. Park 2016	Robotic	62	Not Reported	98	37.3	8.1
	MIE	43		98	28.7	2.3
7. Weksler 2012	Robotic	11	0	100	23 ± 10	9.1
	MIE	26	0	100	23 ± 10	15.4
8. Deng 2018	Robotic	79	0	100	21.5	7.6
	MIE	72	0	100	17.3	5.6
9. He 2018	Robotic	27	Not Reported	Not Reported	20 ± 7	11.11
	MIE	27			19 ± 5	3.70
10. Motoyama 2019	Robotic	21	Not Reported		52	4.8
	MIE	38			59	7.9
11. Zhang 2019	Robotic	76	Not Reported	100	19.7	9.2
	MIE	108		99.1	20.3	5.6
12. Tagkalos 2019	Robotic	50	Not Reported	95	27	12.0
	MIE	50		97.5	23	18.0
13. Harbison 2019	Robotic	100	6.0	Not Reported		14.0
	MIE	625	6.7			15.4
14. Meredith 2019	Robotic	144	Not Reported	100	20	2.8
	MIE[1]	158		60-93.5%	9	5.2
15. Washington 2019	Robotic	18	Not Reported	94.4	14.28	5.6
	MIE	18		94.4	13.9	5.6
16. Chen 2019	Robotic	68	Not Reported	100	25.4	8.8
	MIE	74		100	24.7	2.7
17. Yang 2019	Robotic	271	Not Reported	94.1	20.3	11.8
	MIE	271		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

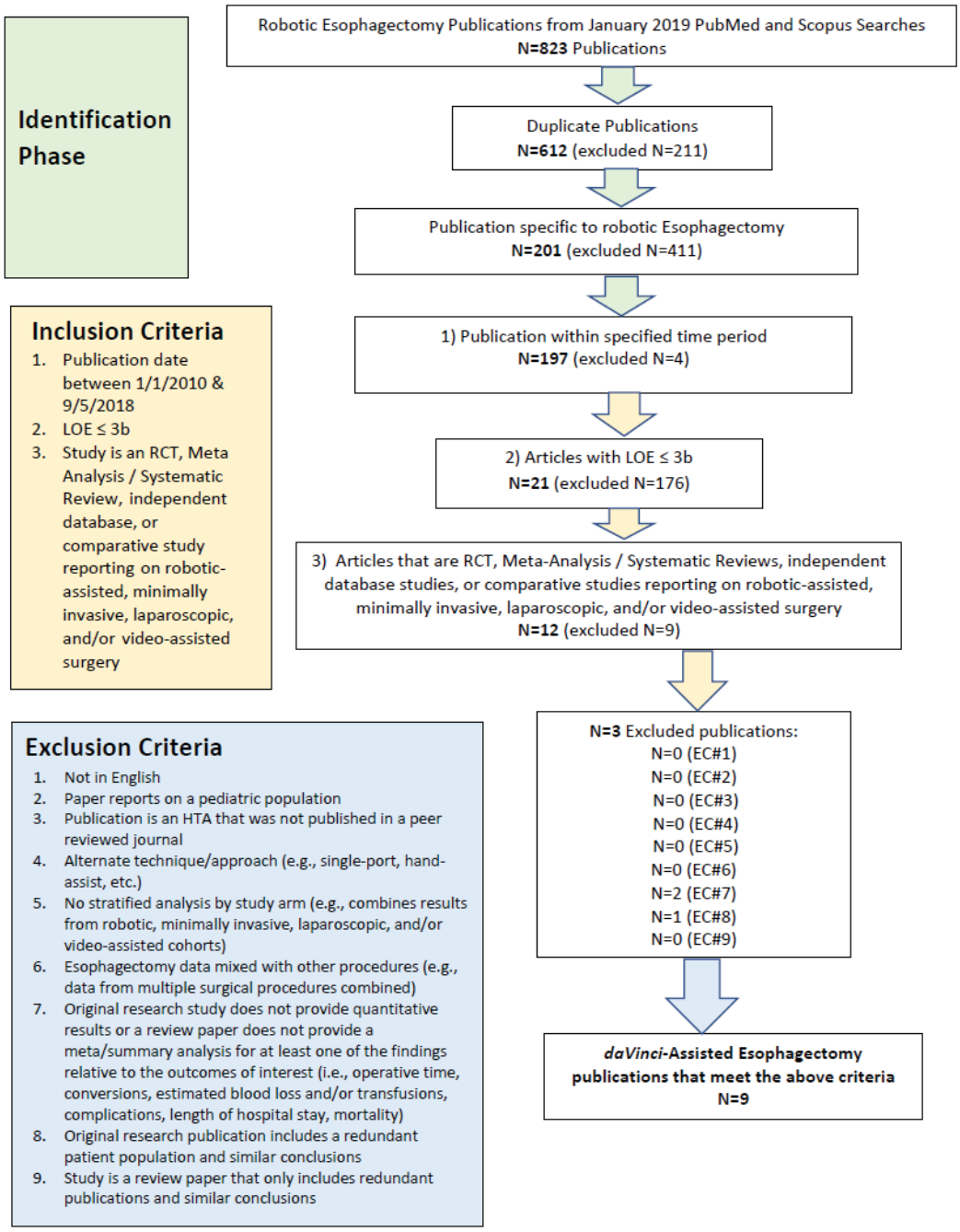

Figure A and the below search terms are associated with the identification of references 1 through 9 listed in Tables 1A and 1B.

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

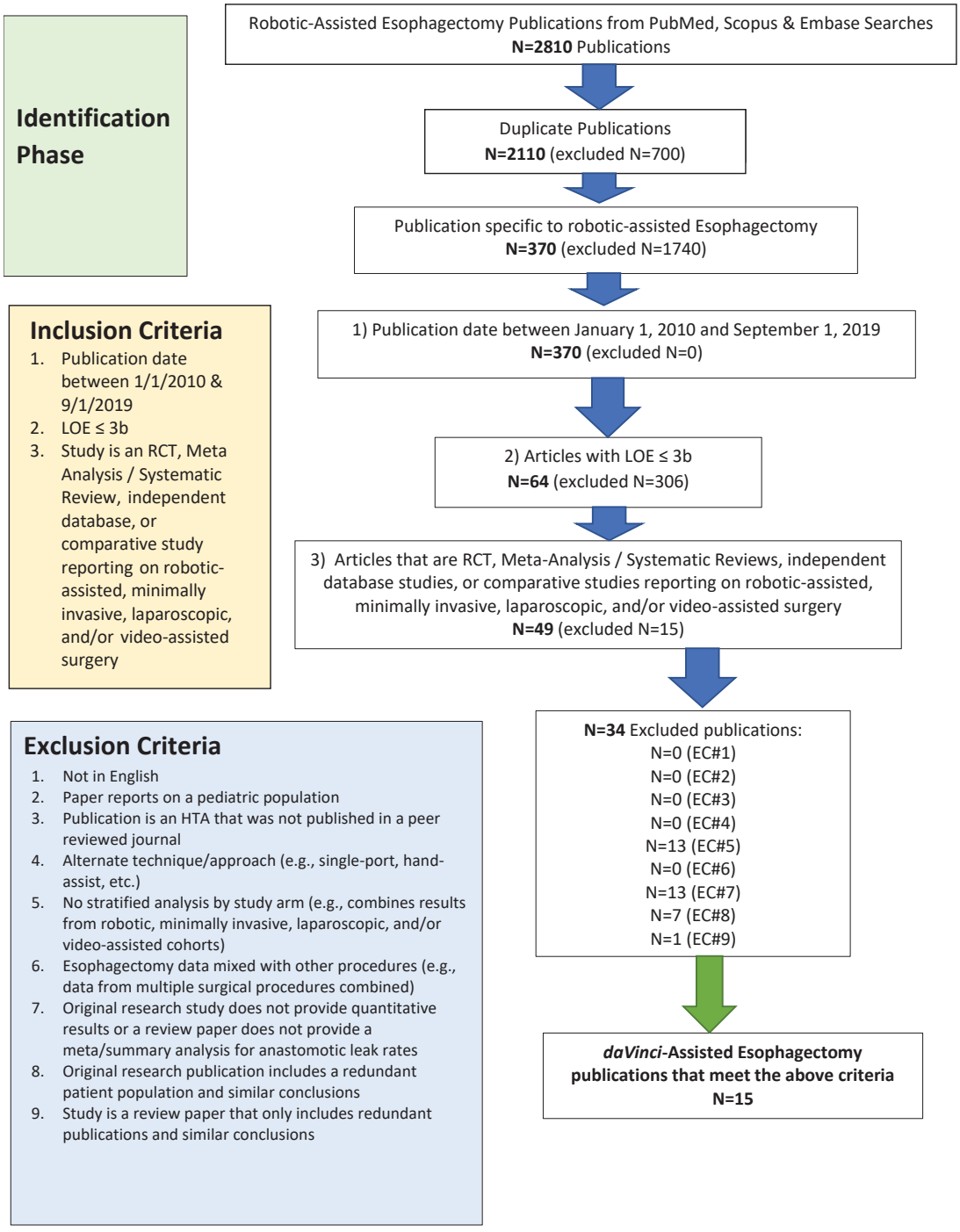

Figure B and the below search terms are associated with the identification of references 3 – 17 listed in Tables 1A and 1B.

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