December 10, 2020

Intuitive Surgical, Inc.
% Cindy Domecus
Principal, Domecus Consulting Services, LLC/ISI Chief Regulatory Advisor
Domecus Consulting Services LLC
1171 Barroilhet Drive
Hillsborough, California 94010

Re: K202834
Trade/Device Name: da Vinci Xi Surgical System (IS4000), da Vinci X Surgical System (IS4200)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: NAY
Dated: September 24, 2020
Received: September 25, 2020

Dear Cindy Domecus:

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,

Je Hi An, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K202834

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)

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:

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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K202834

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.

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510(k) Summary (21 CFR § 807.92(c))
K202834

I. SUBMITTER INFORMATION

Submitter: Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, CA 94086

Contact: Cindy Domecus, R.A.C. (US & EU)
Principal, Domecus Consulting Services LLC
Chief Regulatory Advisor to Intuitive Surgical, Inc.
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Date Summary Prepared: December 7, 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, K182140, K183086)
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 foregut procedures under the cleared "general laparoscopic surgical procedures" Indications for Use of the *da Vinci Xi* Surgical System, Model IS4000 (K131861) and the *da Vinci X* Surgical System, Model IS4200 (K171294): Heller Myotomy, Hiatal/Paraesophageal/Sliding Hernia Repair, Dor Fundoplication and Toupet Fundoplication. 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 representative, specific "foregut" procedures as labeled uses under the cleared "general laparoscopic surgical 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 the 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 the subject representative, specific foregut procedures that fall under the cleared "general laparoscopic surgical procedures" Indication for Use. Clinical data were not provided for all of the representative, specific procedures. Instead, clinical data were provided only for the most complex/highest risk representative, specific procedures: Heller Myotomy and Hiatal/Paraesophageal/Sliding Hernia Repair (referred to as "umbrella" procedures). The published data for these "umbrella" procedures were deemed sufficient to cover the less complex/lower risk

procedures (referred to as "covered" procedures), so published clinical data on the covered procedures of "Dor Fundoplication" and "Toupet Fundoplication" were not provided.

Fifteen (15) publications were identified for the two (2) umbrella procedures based on specific search criteria and filters used in three (3) databases: PubMed, Scopus and Embase. The search terms, inclusion/exclusion criteria and a flowchart depicting the results from these searches is provided in **Figure A**. These publications included: two (2) systematic reviews/meta-analyses (LOE 2a); one (1) prospective study (LOE 2b); two (2) database studies (LOE 2c) and ten (10) retrospective studies (LOE 3b) comparing *da Vinci*-assisted procedures with minimally invasive/ laparoscopic cohorts. Detailed summaries of the published clinical data on these procedures are provided in **Tables 1A** and **1B**.

Umbrella Procedure #1: Heller Myotomy
The findings from the Heller Myotomy publications demonstrate that *da Vinci*-assisted procedures as compared to minimally invasive/laparoscopic procedures are found to be substantially equivalent based on the following endpoints:

- Mortality Rates
- Estimated Blood Loss (EBL) Volumes
- Lengths of Hospital Stay (LOS)
- Intraoperative Complication Rates
- Post/Peri-Operative Complication Rates
- Conversion Rates
- Readmission Rates
- Perforation Rates
- Operative Times

Umbrella Procedure #2: Hiatal/Paraesophageal/Sliding Hernia Repair
The findings from the Hiatal/Paraesophageal/Sliding Hernia Repair publications demonstrate that *da Vinci*-assisted procedures as compared to minimally invasive/laparoscopic 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
- Operative Times

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 representative, specific "foregut" procedures under the "general laparoscopic surgical procedure" Indications for Use 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 Heller Myotomy Procedures

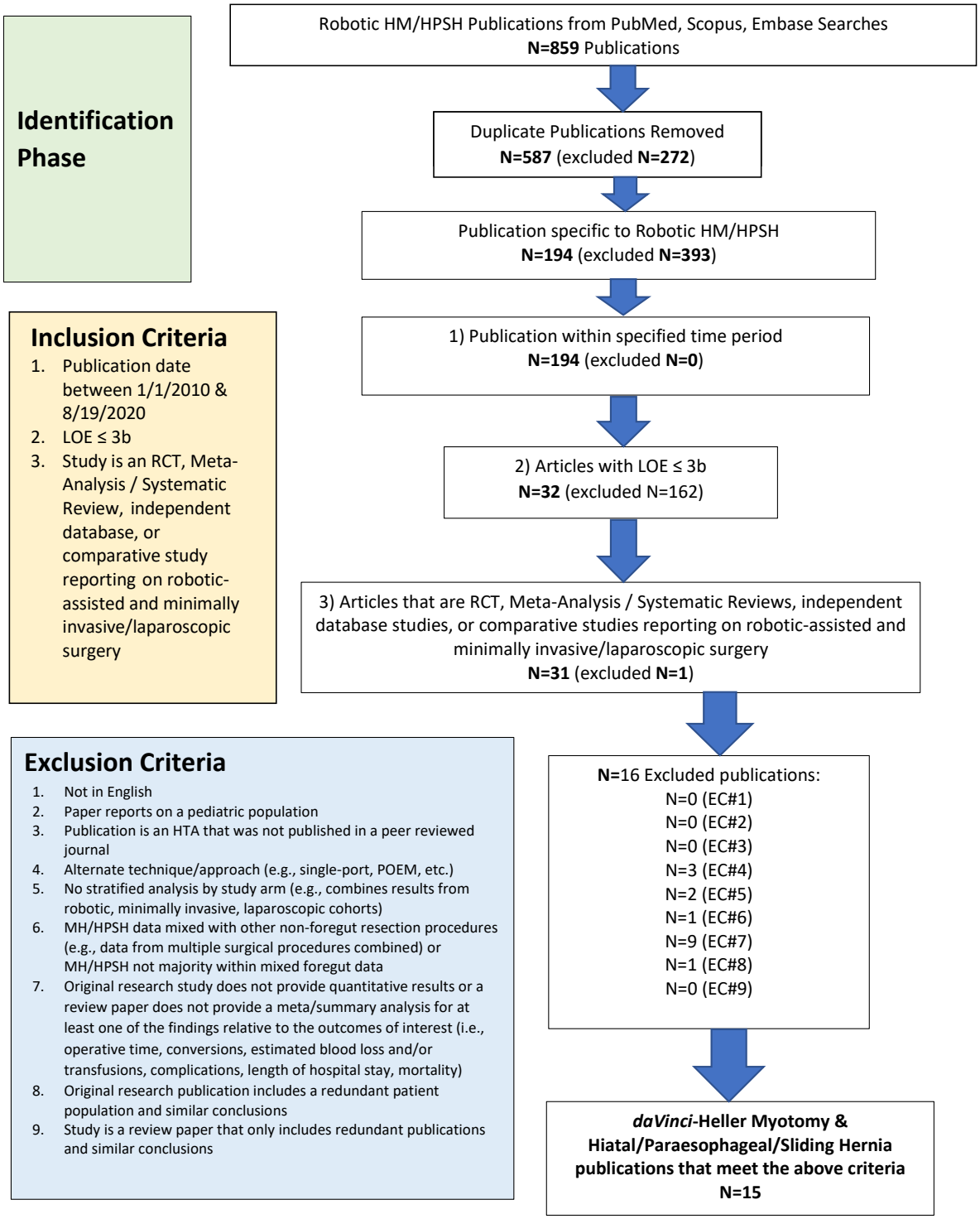
Author/Year	Study Size (N)		Operation Time (minutes)	EBL (ml)	Length of Stay (days)	Intraop Comp Rate (%)	Post/Peri-Op Comp Rate (%)	Mortality (in-hospital - 30 days, %)	Reoperation Rate (%)	Readmission Rate (%)	Conversion Rate (%)	Perforation (%)
1. Ali (2019)	Robotic	44	Median: 183.5	Not Reported	Median: 1	0	Not Reported	0	Not Reported	2.3	0	0
	Lap	40	Median: 157		Median: 1	15		0	2.5	7.5	5	2.5
2. Kim (2018)	Robotic	37	158	41	2.02	Not Reported	0	0			0	2.7
	Lap	35	157	56	2.17		0	0			8.6	11.4
3. Maseo (2010)	Robotic	102	202.9 ± 97.0	Not Reported								0
	Lap	150	183.7 ± 79.8									11
4. Milone (2019)	Robotic	338	164.9 ± 74.7	36.4 ±13.6	2.3 ±0.5	Not Reported					0	3.0
	Lap	2287	159.9 ± 70.2	45.8 ±11.6	2.4 ±0.2						3.0	12.2
5. Perry (2014)	Robotic	56	133 ± 29	25	Median: 1	Not Reported		0	Not Reported		0	0
	Lap	19	121 ± 22	50	Median: 2			0			0	15.8
6. Sanchez (2012)	Robotic	13	79 ± 20	Not Reported		0	Not Reported				0	0
	Lap	18	76 ± 13			5.5					0	5.5
7. Shaligram (2011)	Robotic	149	Not Reported		2.42	Not Reported	4.02	0	Not Reported	2.84	Not Reported	
	Lap	2116			2.70		5.19	0.14		1.41		
8. Villamere (2014)	Robotic	314	Not Reported		2.26	Not Reported	1.27	0	Not Reported	0.66	Not Reported	
	Lap	3135			2.78		1.02	0		1.5		

TABLE 1B: *da Vinci* vs. Minimally Invasive/Laparoscopic Hiatal/Paraesophageal/Sliding Hernia Repair Procedures

Author/Year	Study Size (N)		Operation Time (minutes)	EBL (ml)	Length of Stay (days)	Intraop Comp Rate (%)	Postop Comp Rate (%)	Mortality (in-hospital - 30 days, %)	Reoperation Rate (%)	Readmission Rate (%)	Conversion Rate (%)
1. Gehrig (2013)	Robotic	12	172 ± 31	33 ± 85	7.8 ± 3.9	8.3	8.3	0	8.3	Not Reported	0
	Lap	17	168 ± 42	24 ± 42	6.5 ± 1.6	5.9	11.8	0	0		5.9
2. Gerull (2020)	Robotic	830	174.1 ± 63	27.3 ± 5.9	1.8 ± 0.6	Not Reported		0	0.2	Not Reported	0
	Lap	1024	1 87.3 ± 65	89.3 ± 27.8	2.9 ± 1.4			0.5	0.8		7.0
3. Hosein (2020)	Robotic	835	Not Reported		3.44 ± 5.01	Not Reported	2	0.1	Not Reported		
	Lap	6774			3.9 ± 5.22		3.7	0.4			
4. Howell (2020)	Robotic	44	Not Reported		Median: 2.0	Not Reported	13.6	0	0	4.6	0
	Lap	84			Median: 1.0		11.9	0	2.4	8.3	0
5. O'Connor (2020)	Robotic	114	179	Not Reported	2.3	Not Reported					
	Lap	279	175		3.3						
6. Soliman (2019)	Robotic	142	186.5	1.4^	1.3 ± 1.8	Not Reported	6.3	0	1.4	3.50	0.7
	Lap	151	158.0	2.0^	1.8 ± 1.5		19.2	0	2.0	4.00	0
7. Tolboom (2016)	Robotic	45	120	Not Reported	Median: 1.0	15.56	Not Reported	0	8.89	ICU: 0	2.2
	Lap	30	95		Median: 4.0	13.3		0	13.33	ICU: 6.67	16.7

^Post-operative blood transfusion rates reported

FIGURE A: Search Criteria & Flowchart for Identification of Heller Myotomy, Hiatal/Paraesophageal/Sliding Hernia Repair Publications



PubMed Search Terms: robotic, robot, robot assist, robotically assisted, robot assist, da vinci, davinci, intuitive surgical, robot surgery, achalasia, achalasias, heller myotomy, cardiospasm, cardiomyotomy, foregut, hiatal hernia, paraesophageal hernia, hernia, paraesophageal, sliding hernia
Scopus Search Terms: davinci, robotic surgery, intuitive surgical, robotic assist, robot surgery, robotic assist, achalasia, achalasias, esophageal achalasia, heller myotomy, foregut, hiatal hernia, paraesophageal hernia, hernia, paraesophageal, sliding hernia
Embase Search Terms: da vinci, davinci, intuitive surgical, endowrist, achalasia, achalasias, esophagus achalasia, heller myotomy, foregut, hiatal hernia, paraesophageal hernia, hernia, paraoesophageal, sliding hernia