



January 31, 2018

Intuitive Surgical, Inc.
% Ms. Cindy Domecus
Domecus Consulting Services LLC
1171 Barroilhet Drive
Hillsborough, California 94010

Re: K172643

Trade/Device Name: da Vinci Xi Surgical System, da Vinci X Surgical System; Model IS4000 and Model IS4200

Regulation Number: 21 CFR 876.1500

Regulation Name: Endoscope and Accessories

Regulatory Class: Class II

Product Code: NAY

Dated: January 29, 2018

Received: January 31, 2018

Dear Ms. 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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -

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For Binita S. Ashar, M.D., M.B.A., F.A.C.S.

Director

Division of Surgical Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K172643

Device Name

da Vinci Surgical System, Model IS4000, and EndoWrist Instruments and Accessories

Indications for Use (Describe)

The Intuitive Surgical Endoscopic Instrument Control System (da Vinci 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 cardiectomy 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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Indications for Use

510(k) Number (if known)

K172643

Device Name

da Vinci Surgical System, Model IS4200, and EndoWrist Instruments and Accessories

Indications for Use (Describe)

The Intuitive Surgical Endoscopic Instrument Control System (da Vinci 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 cardiectomy 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: Cindy Domecus, R.A.C. (US & EU)
Principal, Domecus Consulting Services LLC
Chief Regulatory Advisor to Intuitive Surgical
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Date Summary Prepared: January 16, 2018

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 Device: Intuitive Surgical *da Vinci Xi and X* Surgical Systems, Models IS4000 and IS4200 (K131861, K152578, K153276, K161178, K170713, K171294)
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 procedures under the cleared “general laparoscopic surgical procedures” Indication for Use of the *da Vinci Xi* Surgical System, Model IS4000 (K131861) and the *da Vinci X* Surgical System, Model IS4200 (K171294): Pancreatectomy (partial, distal, segmental), Pancreaticoduodenectomy (Whipple Procedure), Splenectomy and Cholecystectomy. 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 cardiectomy 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 was based on evaluation of the device as a surgical tool and 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 TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

There are no changes to the technological characteristics of the cleared *da Vinci* Xi or X Surgical Systems (IS4000 and IS4200) proposed in this submission.

VII. PERFORMANCE DATA

Pre-Clinical Animal Study Data

Animal performance data were provided in this premarket notification, including the results from seven (7) evaluations in a total of 27 animals demonstrating use of *da Vinci Xi* Surgical System (Model IS4000) in the following procedures: Nephrectomy, Pyeloplasty, Hysterectomy and Salpingectomy/Oophorectomy (Adnexectomy), Nissen Fundoplication, Colectomy, Mitral Valve Repair and Splenectomy. These data were previously submitted in support of clearance of the *da Vinci Xi* Surgical System, Model IS4000 (K131861), the *da Vinci Xi* Vessel Sealer (K140189/S001) and the *da Vinci Xi* (Model IS4000) labeling modification to add specific procedures under the gynecologic laparoscopic surgical procedures general indication (K152578); general thoracoscopic surgical procedures and thoracoscopically-assisted cardiectomy procedures indication (K153276); urologic surgical procedures general indication (K161178); and, general laparoscopic surgical procedures general indication (K170713 and K171632). These data also support inclusion of the subject representative, specific procedures.

Clinical Study Data

Published clinical data support use of the *da Vinci Xi and X* Surgical Systems (Models IS4000 and IS4200) in the subject representative, specific 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 of Pancreatectomy and Pancreaticoduodenectomy (Whipple Procedure) (referred to as the “umbrella” procedures). The published data on 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 were not provided.

Umbrella Procedures

Umbrella Procedure #1: Pancreatectomy

Published clinical data were provided for the umbrella procedure “Pancreatectomy”. Eleven (11) publications were identified for this umbrella procedure based on specific search criteria and filters. These publications included a prospective randomized controlled trial, meta-analyses, systematic reviews and large database comparative studies. A detailed summary of the published clinical data on this procedure is provided in **Tables 1A** and **1B** below.

The findings from the Pancreatectomy publications show that *da Vinci*-assisted procedures as compared to open and laparoscopic procedures are associated with:

- Mortality: comparable mortality rates;
- Estimated Blood Loss and/or Transfusion Rates: comparable or lower blood transfusion rates and/or EBL volumes;
- Lengths of Hospital Stay: comparable or shorter length of hospital stay as compared to laparoscopy and open surgery;
- Complication Rates: comparable or lower complication rates;
- Spleen Preservation Rates: higher or comparable spleen preservation rates;
- Gastric Emptying Rates: lower or comparable delayed gastric emptying rates;
- Reoperation Rates: comparable reoperation rates;
- Readmission Rates: comparable or higher readmission rates; and
- Pancreatic Fistula Rates: comparable pancreatic fistula rates as compared to both open and laparoscopic surgical procedures.
- Operative Time: Increased operative times were associated with *da Vinci* procedures as compared to open and laparoscopic procedures. However, this increase was not associated with an increase in the mortality or complication rates.
- Conversion Rates: comparable or lower conversion rates were reported for *da Vinci*-assisted procedures as compared to laparoscopic procedures.

Umbrella Procedure #2: Pancreaticoduodenectomy

Published clinical data were provided for the umbrella procedure “Pancreaticoduodenectomy”. Eight (8) publications were identified for this umbrella procedure based on specific search criteria and filters. These publications included meta-analyses, systematic reviews and a large database comparative study. A detailed summary of the published clinical data on this procedure is provided in **Tables 2A** and **2B** below.

The findings from the Pancreaticoduodenectomy publications show that *da Vinci*-assisted procedures as compared to open and laparoscopic procedures are associated with:

- Mortality: comparable mortality rates;
- Estimated Blood Loss Volume¹: comparable EBL volumes;
- Lengths of Hospital Stay: comparable length of hospital stay as compared to laparoscopy and comparable or shorter length of hospital stay as compared to open surgery;
- Complication Rates: comparable or lower complication rates;
- Gastric Emptying Rates: lower or comparable delayed gastric emptying rates;
- Reoperation Rates: comparable reoperation rates; and,
- Pancreatic Fistula Rates: comparable pancreatic fistula rates as compared to both open and laparoscopic surgical procedures.
- Operative Time: Increased operative times were associated with *da Vinci* procedures as compared to open and laparoscopic procedures. However, this increase was not associated with an increase in the mortality or complication rates.
- Conversion Rates: comparable or lower conversion rates for *da Vinci*-assisted procedures were reported as compared to laparoscopic procedures.

Covered Procedures

The published data on the above cited Pancreatectomy and Pancreaticoduodenectomy (Whipple Procedure) umbrella procedures were used to support clearance of the following covered procedures: Splenectomy and Cholecystectomy.

VIII. CONCLUSION

Based on the information provided in this premarket notification, the inclusion of the following additional representative, specific procedures under the *da Vinci Xi* and *X Surgical Systems* (Models IS4000 and IS4200) “general laparoscopic surgical procedure” Indication for Use is substantially equivalent to the predicate devices: Pancreatectomy (partial, distal, segmental), Pancreaticoduodenectomy (Whipple Procedure), Splenectomy and Cholecystectomy.

¹ One publication (Orti-Rodriguez, et al) reported a higher EBL volume, a longer length of stay and a higher pancreatic fistula rate for the *da Vinci* cohort as compared to the laparoscopic cohort. These outcomes were not associated with increased complication or mortality rates.

TABLE 1A: *da Vinci* vs. Open and *da Vinci* vs. Laparoscopic Pancreatectomy

Publications	Sample Size (N)		Operative Time (minutes)	Estimated Blood Loss "EBL" (ml)	Length of Stay (days)	PostOp Complications (%)	Mortality Rate (%)	Transfusion Rate (%)	Reoperation Rate (%)	Readmission Rate (%)
1. Adam (2015)	<i>da Vinci</i>	61	Not Reported	Not Reported	8	Not Reported	0	Not Reported	Not Reported	Suppressed 12.9
	Lap	474			6		suppressed			11
	Open	1198			9		2			9
2. Chen S (2017)	<i>da Vinci</i>	50	160	50	15.6	46	0	0	4	2
	Open	50	193	200	21.7	60	0	10	8	2
3. Chen Y (2013)	<i>da Vinci</i>	67 /45	range (293 - 719)	range (150 - 372)	range (3.8 - 16.4)	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported
	Lap	137	range (224 - 372)	range (150 - 667)	range (6.4 - 7.3)					
	Open	45	range (234 - 420)	range (210 - 858)	range (7.7 - 24.3)					
4. Gavriliadis (2016)	<i>da Vinci</i>	246	range (213 - 349)	Not Reported	range (5 - 11.6)	16	0.4	Not Reported	Not Reported	5.6 - 36.7
	Lap	391	range (174 - 372)		range (6.0 - 14.7)	17	0.3			0 - 23.4
5. Huang (2016)	<i>da Vinci</i>	238	range (293 - 349)	Not Reported	range (6.1 - 8.9)	Not Reported	0	13.9	Not Reported	Not Reported
	Lap	929	range (250 - 372)		range (6.0 - 19.2)		0	11.4		
6. Konstantinidis (2017)	<i>da Vinci</i>	115	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported
	Lap	365								
	Open	558								
7. Wright (2016)	<i>da Vinci</i>	195	230	172	8	18	0	Not Reported	Not Reported	Not Reported
	Lap	349	249	281	7	17	<1			
8. Xourafas (2017)	<i>da Vinci</i>	200	243	Not Reported	5	37	0.5	6	3	17
	Lap	694	205		5	36	1	5	3	14
	Open	921	222		7	45	1.5	21	5	18
9. Zhang (2013)	<i>da Vinci</i>	22	range (298 - 432)	range (275 - 279)	range (4 - 14.6)	17.6 - 20*	0	Not Reported	0	Not Reported
	Open	32	range (234 - 286.5)	range (681 - 858.3)	range (8 - 22.1)	18.2 - 50*	0		2	
10. Zhou (2016)	<i>da Vinci</i>	211	range (150 - 372)	range (100 - 375)	range (3.8 - 11.6)	43.6	1.4	8.3	Not Reported	Not Reported
	Lap	357	range (193 - 295)	range (262 - 667)	range (5 - 14.7)	52.4	2.0	11.1		
11. Zureikat (2017)	<i>da Vinci</i>	258	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported
	Lap	684								
	Open	3743								

*Authors reported on "Overall Complication Rate"

TABLE 1B: *da Vinci* vs. Open and *da Vinci* vs. Laparoscopic Pancreatectomy

Publications	Sample Size (N)		Spleen Preservation Rate (%)	R0 Resection Rate (%)	R1 Resection Rate (%)	Lymph Node Yield (n)	Delayed Gastric Emptying Rate (%)	Pancreatic Fistula Rate (%)	Conversion Rate (%)
1. Adam (2015)	<i>da Vinci</i>	61	Not Reported	Not Reported	Not Reported	12	Not Reported	Not Reported	suppressed 14.8
	Lap	474				12			23
	Open	1198				13			NA
2. Chen S (2017)	<i>da Vinci</i>	50	Not Reported	Not Reported	Not Reported	Not Reported	A (12), B (6), C (6)	44	Not Reported
	Open	50					A (22), B (8), C (4)	54	
3. Chen Y (2013)	<i>da Vinci</i>	67 /45	81.1	98	Not Reported	Not Reported	Not Reported	30.2	Not Reported
	Lap	137	48.8	83				36.6	
	Open	45	13.6	82				31.1	
4. Gavrilidis (2016)	<i>da Vinci</i>	246	Not Reported	100	0	Not Reported	Not Reported	24.3	9
	Lap	391		98	2			24.0	20
5. Huang (2016)	<i>da Vinci</i>	238	35.4	Not Reported	Not Reported	Not Reported	Not Reported	29.9	8.9
	Lap	929	27.7					31.3	23.0
6. Konstantinidis (2017)	<i>da Vinci</i>	115	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	11.3
	Lap	365							21.9
	Open	558							NA
7. Wright (2016)	<i>da Vinci</i>	195	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	10
	Lap	349							19
8. Xourafas (2017)	<i>da Vinci</i>	200	8	Not Reported	Not Reported	Not Reported	1	21	8
	Lap	694	9				3	18	16
	Open	921	10				5	17	NA
9. Zhang (2013)	<i>da Vinci</i>	22	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	4.5	0 - 12
	Open	32						25.0	NA
10. Zhou (2016)	<i>da Vinci</i>	211	53.6	100	Not Reported	range (5 – 19)	Not Reported	25.8	16.1
	Lap	357	27.8	92.6		range (5 – 15.2)		24.7	23.0
11. Zureikat (2017)	<i>da Vinci</i>	258	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	10
	Lap	684							18.2
	Open	3743							NA

*Authors provided combined data for pancreatectomy and pancreaticoduodenectomy procedures.

TABLE 2A: *da Vinci* vs. Open and *da Vinci* vs. Laparoscopic Pancreaticoduodenectomy

Publications	Sample Size (N)		Operative Time (minutes)	Estimated Blood Loss "EBL" (ml)	Length of Stay (days)	PostOp Complications (%)	Mortality Rate (%)	Transfusion Rate (%)	Reoperation Rate (%)	Readmission Rate (%)
1. de Rooij (2016)	<i>da Vinci</i>	160	Not Reported	Not Reported	Not Reported	Not Reported	2.5	Not Reported	Not Reported	Not Reported
	Lap	641					3.0			
	Open	1123					3.7			
2. Lei P (2014)	<i>da Vinci</i>	102	range (444 - 719)	range (154 - 485)	range (13 - 16.4)	43.14**	Not Reported	Not Reported	Not Reported	Not Reported
	Lap	107	range (338 - 657)	range (195 - 448)	range (8 - 48)	57.01**				
	Open	144 / 285	range (265 - 559)	range (210 - 1510)	range (12.4 - 43)	54.9 / 65.3**				
3. Orti-Rodriguez (2012)	<i>da Vinci</i>	109	394.77	319.06	15.31	16.5	3	Not Reported	Not Reported	Not Reported
	Lap	192	388.8	178.7	9.9	35.9	2.7			
4. Pedziwiatr (2017)	<i>da Vinci</i>	476	range (400 - 718)	range (100 - 775)	range (7.4 - 20.0)	37.7	Not Reported	Not Reported	Not Reported	Not Reported
	Lap	229	range (361 - 513)	range (260 - 492.4)	range (6.0 - 10.0)	59.5				
	Open	1162 / 319	range (300 - 559)	range (210 - 867)	range (8.0 - 25.8)	31.9 / 80.0				
5. Peng (2016)	<i>da Vinci</i>	245	range (410 - 718.8)	range (100 - 650)	range (13 - 20)	35	2.9	Not Reported	7.3	Not Reported
	Open	435	range (264.9 - 559)	range (210 - 840)	range (14.6 - 25.8)	45	2.8		13.0	
6. Shin (2016)	<i>da Vinci</i>	160	range (340 - 492)	range (100 - 500)	range (7 - 20)	37.1	Not Reported	Not Reported	Not Reported	Not Reported
	Lap	450	range (342 - 551)	range (195 - 609)	range (6 - 25)	40.8				
	Open	294 / 718	range (264 - 410)	range (293 - 1032)	range (8 - 26)	47.7 / 50.9				
7. Zhang (2013)	<i>da Vinci</i>	115	range (444 - 718.8)	range (153.75 - 537)	range (7 - 16.38)	25 - 36.4*	0 - 4.5	Not Reported	6.5	Not Reported
	Open	171	range (364 - 559)	range (210 - 840)	range (13.26 - 24.25)	23.2 - 75*	0 - 12.5		18.6	
8. Zureikat (2017)	<i>da Vinci</i>	258	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported
	Lap	684								
	Open	3743								

*Authors reported on "Overall Complication Rate"; **Authors reported both intraoperative and post-operative complication rates.

TABLE 2B: *da Vinci* vs. Open and *da Vinci* vs. Laparoscopic Pancreaticoduodenectomy

Publications	Sample Size (N)		Spleen Preservation Rate (%)	R0 Resection Rate (%)	R1 Resection Rate (%)	Lymph Node Yield (n)	Delayed Gastric Emptying Rate (%)	Pancreatic Fistula Rate (%)	Conversion Rate (%)
1. de Rooij (2016)	da Vinci	160	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	7.6	8
	Lap	641						12.7	7
	Open	1123						18.4	NA
2. Lei P (2014)	da Vinci	102	Not Reported	Not Reported	Not Reported	Not Reported	4.3	20.6	Not Reported
	Lap	107					13.1	23.4	
	Open	144 / 285					7.4 / 13.7	19.4 / 17.5	
3. Orti-Rodriguez (2012)	da Vinci	109	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	30	12
	Lap	192						14.5	8.3
4. Pedziwiatr (2017)	da Vinci	476	Not Reported	Not Reported	35.5	range (15 - 37)	23.7	20.2	Not Reported
	Lap	229			20.7	range (8.7 - 23)	8.7	15.7	
	Open	1162 / 319			29.5 / 23.0	range (9.6 - 36)	20.1 / 17.2	12.7 / 17.6	
5. Peng (2016)	da Vinci	245	Not Reported	93.1	Not Reported	range (10.0 - 16.8)	6.8	17.9	7.3
	Open	435		81.5		range (10.0 - 12.5)	14.1	21.4	NA
6. Shin (2016)	da Vinci	160	Not Reported	Not Reported	13.4	range (10 - 15)	8.8	18.5	7.5
	Lap	450			21.6	range (8.7 - 23.4)	9.6	29.8	7.8
	Open	294 / 718			22.8 / 22.1	range (9.6 - 25.0)	15.6 / 14.2	21.6 / 23.0	NA
7. Zhang (2013)	da Vinci	115	Not Reported	Not Reported	3.1	Not Reported	Not Reported	14.4	Not Reported
	Open	171			14.8			22.0	
8. Zureikat (2017)	da Vinci	258	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	14.8
	Lap	684							31.9
	Open	3743							NA