



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: K211784

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: June 4, 2021  
Received: June 9, 2021

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark Trumbore Ph.D., GWCPM  
Acting Assistant Director  
THT4A1: Robotically-Assisted Surgical Devices Team  
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

## Indications for Use

510(k) Number (if known)

K211784

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 cardiomy 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.

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## Indications for Use

510(k) Number (if known)

K211784

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 cardiomy 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)  
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Chief Regulatory Advisor to Intuitive Surgical, Inc.  
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**Date Summary Prepared:** June 4, 2021

### 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, K202834)  
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 of “Hepatectomy/Liver Resection” 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). 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 cardiomy 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 the representative, specific procedure of "Hepatectomy/Liver Resection" as a labeled use 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 procedure of "Hepatectomy/Liver Resection" that falls under the cleared "general laparoscopic surgical procedures" Indication for Use. Thirty-eight (38) publications were identified for the subject procedure 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: one (1) prospective study (LOE 2b); five (5) database studies (LOE 2c) and thirty-two (32)

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**.

The findings from the Hepatectomy/Liver Resection 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
- Transfusion Rates
- Lengths of Hospital Stay (LOS)
- Post/Peri-Operative Complication Rates
- Conversion Rates
- Readmission Rates
- Perforation Rates
- Operative Times
- Biliary/Bile Leak Rates
- Liver Failure Rates

#### **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 the representative, specific procedure of: “Hepatectomy/Liver Resection” 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 Hepatectomy/Liver Resection Procedures**

| Author                                     | Study Size (N) | Operation Time (minutes)              | Conversion to Open Rate (%) | Peri / Postoperative Complication Rate (%) | EBL (ml)        | Transfusion Rate (%) | Mortality Rate (%) (in-hospital, 30, 90 days) | Length of Stay (days) | Reoperation Rate (%) | Readmission Rate (%) |
|--------------------------------------------|----------------|---------------------------------------|-----------------------------|--------------------------------------------|-----------------|----------------------|-----------------------------------------------|-----------------------|----------------------|----------------------|
| <b>1. Efanov 2017</b>                      | Robotic        | 407 (85-980)                          | 5%                          | 20%                                        | 465 (0-2000)    | 8%                   | 0% <sup>^</sup>                               | 11 (6-30)             | 2.5%                 | Not Reported         |
|                                            | Lap            | 296 (70-605)                          | 4%                          | 17%                                        | 302 (0-2200)    | 4%                   | 0% / 1.1% <sup>^</sup>                        | 9 (4-90)              | 1.1%                 |                      |
| <b>2. Lim 2019</b><br>unmatched<br>matched | Robotic        | 277 ± 156                             | 3.2%                        | 25%                                        | Not Reported    | 14.8%                | 0%                                            | 9 ± 12                | 1.6%                 | 0%                   |
|                                            | Lap            | 263 ± 109                             | 11.2%                       | 15%                                        |                 | 1.8%                 | 0%                                            | 7 ± 6                 | 0%                   | 0.9%                 |
|                                            | Robotic        | 254 ± 143                             | Not Reported                | 22%                                        |                 | 10.9%                | 0%                                            | 9 ± 13                | 1.8%                 | 0%                   |
|                                            | Lap            | 257 ± 102                             | Reported                    | 13%                                        |                 | 3.6%                 | 0%                                            | 7 ± 5                 | 0%                   | 0%                   |
| <b>3. Spampinato 2014</b>                  | Robotic        | 430 (240-725)                         | 4.0%                        | 16%                                        | 250 (100-1900)  | 44%                  | 0% <sup>^</sup>                               | 8 (4-22)              | 4.0%                 | 0% <sup>^</sup>      |
|                                            | Lap            | 360 (180-600)                         | 4.0%                        | 36%                                        | 400 (50-1200)   | 16%                  | 4% <sup>^</sup>                               | 7 (5-22)              | 4.0%                 | 4% <sup>^</sup>      |
| <b>4. Berber 2010</b>                      | Robotic        | 258.5 ± 27.9                          | 11.1%                       | 11.1%                                      | 136 ± 61        | Not Reported         | Not Reported                                  | Not Reported          |                      |                      |
|                                            | Lap            | 233.6 ± 16.4                          | 0.0%                        | 17.4%                                      | 155 ± 54        |                      |                                               |                       |                      |                      |
| <b>5. Chong 2019</b>                       | Robotic        | 259.3 ± 127.0                         | 7.7%                        | 9.9%                                       | 274.6 ± 568.1   | Not Reported         | Not Reported                                  | 4.8 ± 1.8             | Not Reported         | Not Reported         |
|                                            | Lap            | 216.8 ± 79.2                          | 12.0%                       | 5.4%                                       | 212.4 ± 313.3   |                      |                                               | 4.9 ± 2.0             |                      |                      |
| <b>6. Croner 2016</b>                      | Robotic        | 321 (138-458)                         | Not Reported                | 10%                                        | 306             | Not Reported         | 0%                                            | 7 (5-13)              | 0%                   | Not Reported         |
|                                            | Lap            | 242 (80-478)                          | Reported                    | 16%                                        | 356             | Reported             | 5.0%                                          | 8 (4-33)              | 0%                   |                      |
| <b>7. Fruscione 2019</b>                   | Robotic        | 194 (152-255)                         | Not Reported                | 28.1%                                      | 250 (125-600)   | Not Reported         | 0%                                            | 4 (3-5)               | 1.8%                 | 7.0% <sup>^</sup>    |
|                                            | Lap            | 204 (149-280)                         | Reported                    | 35.3%                                      | 400 (150-750)   | Reported             | 0%                                            | 5 (3-6)               | 0.9%                 | 28.4% <sup>^</sup>   |
| <b>8. Hu 2019</b>                          | Robotic        | 107.0 ± 45.2                          | 0%                          | 2%                                         | 80.1 ± 144.4    | 5.2%                 | 0%                                            | 4.3 ± 1.8             | Not Reported         | Not Reported         |
|                                            | Lap            | 95.7 ± 47.5                           | 1.9%                        | 4%                                         | 108.9 ± 180.8   | 1.9%                 | 0%                                            | 4.4 ± 1.8             |                      |                      |
| <b>9. Lai 2016</b>                         | Robotic        | 207.4 ± 77.1                          | 4.0%                        | 14%                                        | 334.6 (5-3500)  | 9.0%                 | 0%                                            | 7.3 ± 5.3             | Not Reported         | Not Reported         |
|                                            | Lap            | 134.2 ± 41.7                          | 5.7%                        | 20%                                        | 336.0 (5-2000)  | 11.4%                | 0%                                            | 7.1 ± 2.6             |                      |                      |
| <b>10. Lee KF 2016</b>                     | Robotic        | 251.5 (97-620)                        | 5.7%                        | 11.4%                                      | 100 (2-2500)    | 4.3%                 | 0%                                            | 5 (2-22)              | 0%                   | Not Reported         |
|                                            | Lap            | 215 (90-420)                          | 12.1%                       | 4.5%                                       | 100 (5-1610)    | 1.5%                 | 0%                                            | 5 (2-15)              | 0%                   |                      |
| <b>11. Lee JS 2019</b>                     | Robotic        | LH: 248.6 ± 37.5<br>LLS: 160.8 ± 33.6 | 0%                          | 7.7%                                       | 320.3 ± 331.9   | 0%                   | 0%                                            | 7.0 ± 2.4             | Not Reported         | Not Reported         |
|                                            | Lap            | LH: 226.7 ± 26.6<br>LLS: 116.3 ± 8.7  | 10%                         | 10%                                        | 392.8 ± 374.5   | 0%                   | 0%                                            | 7.3 ± 2.9             |                      |                      |
| <b>12. Marino 2018</b>                     | Robotic        | 425 ± 139                             | 14.3%                       | 21.4%                                      | 335.15 ± 139.8  | 0%                   | 0%                                            | 9 ± 1.4               | 0%                   | Not Reported         |
|                                            | Lap            | 565.18 ± 183.73                       | 25.0%                       | 15.0%                                      | 423.95 ± 205.15 | 0%                   | 0%                                            | 8.6 ± 1.5             | 5.0%                 |                      |
| <b>13. Mejia 2019</b><br>Minor<br>Major    | Robotic        | 121 [107-178]                         | 0%                          | 0%                                         | 150 [100-200]   | 8.6%                 | 0%                                            | 2 [2-4]               | Not Reported         | Not Reported         |
|                                            | Lap            | 148 [113-180]                         | 1.2%                        | 4.7%                                       | 135 [50-275]    | 4.7%                 | 0%                                            | 3 [2-3]               |                      |                      |
|                                            | Robotic        | 222 [168.5-240.5]                     | 0%                          | 0%                                         | 500 [225-780]   | 25.0%                | 0%                                            | 3 [2.5-5.5]           |                      |                      |
|                                            | Lap            | 195 [180-210]                         | 7.7%                        | 23.1%                                      | 250 [100-300]   | 7.7%                 | 0%                                            | 3 [3-5]               |                      |                      |
| <b>14. Montali 2015</b>                    | Robotic        | 306 ± 182                             | 13.9%                       | 19.4%                                      | 415 ± 414       | Not Reported         | 2.8%                                          | 6 ± 2.9               | Not Reported         | Not Reported         |
|                                            | Lap            | 295 ± 107                             | 9.7%                        | 19.4%                                      | 437 ± 523       | Reported             | 0%                                            | 4.9 ± 2.95            |                      |                      |
| <b>15. Packiam 2012)</b>                   | Robotic        | 175 (156-253)                         | 0%                          | 27%                                        | 30 (30-50)      | 0%                   | 0%                                            | 4 (3-5)               | 0%                   | 9.1%                 |
|                                            | Lap            | 188 (156-222)                         | 0%                          | 0%                                         | 30 (30-30)      | 0%                   | 0%                                            | 3 (2-3)               | 0%                   | 0%                   |



| Author                   | Study Size (N) | Operation Time (minutes) | Conversion to Open Rate (%) | Peri / Postoperative Complication Rate (%) | EBL (ml)        | Transfusion Rate (%) | Mortality Rate (%) (in-hospital, 30, 90 days) | Length of Stay (days) | Reoperation Rate (%) | Readmission Rate (%)                      |
|--------------------------|----------------|--------------------------|-----------------------------|--------------------------------------------|-----------------|----------------------|-----------------------------------------------|-----------------------|----------------------|-------------------------------------------|
| 16. Tranchart 2014       | Robotic        | 210 (45-480)             | 14.3%                       | 17.9%                                      | 200 (0-1,800)   | 14.3%                | 0%                                            | 6 (1-15)              |                      | Not Reported                              |
|                          | Lap            | 176 (30-420)             | 7.1%                        | 17.9%                                      | 150 (0-1,000)   | 3.6%                 | 3.6%                                          | 5.5 (1-50)            |                      | Not Reported                              |
| 17. Troisi 2013          | Robotic        | 271 ± 100                | 20%                         | 12.5%                                      | 330 ± 303       | Not Reported         | 0%                                            | 6.1 ± 2.6             |                      | Not Reported                              |
|                          | Lap            | 262 ± 111                | 7.6%                        | 12.6%                                      | 174 ± 133       | Reported             | 0%                                            | 5.9 ± 3.8             |                      | Not Reported                              |
| 18. Tsung 2013           | Robotic        | 253 (180-355)            | 7%                          | 19.3%                                      | 200 (50-337.5)  | 3.8%                 | 0% <sup>^</sup>                               | 4.0 (3.0-5.5)         |                      | Not Reported                              |
|                          | Lap            | 198.5 (138-262)          | 8.8%                        | 26%                                        | 100 (50-350)    | 7.4%                 | 0.9% / 1.8% <sup>^</sup>                      | 4.0 (3.0-5.0)         |                      | Not Reported                              |
| 19. Wang 2019            | Robotic        | 195.53 ± 67.00           | 1.1%                        | 13%                                        | 243.04 ± 171.87 | Not Reported         | 0%                                            | 7.41 ± 2.64           | 0%                   | Not Reported                              |
|                          | Lap            | 198.98 ± 72.94           | 10.4%                       | 10.4%                                      | 346.04 ± 234.17 | Not Reported         | 0%                                            | 7.06 ± 3.35           | 0%                   | Not Reported                              |
| 20. Wu 2014              | Robotic        | 380 ± 166                | 5.3%                        | 8%                                         | 325 ± 480       | Not Reported         | 0%                                            | 7.9 ± 4.7             |                      | Not Reported                              |
|                          | Lap            | 227 ± 80                 | 12.2%                       | 9.8%                                       | 173 ± 165       | Reported             | 0%                                            | 7.2 ± 4.4             |                      | Not Reported                              |
| 21. Yu 2014              | Robotic        | 291.5 ± 85.1             | 0%                          | 0%                                         | 388.5 ± 65.0    | 0%                   | 0%                                            | 7.8 ± 2.3             |                      | Not Reported                              |
|                          | Lap            | 240.9 ± 68.6             | 0%                          | 11.8%                                      | 342.6 ± 84.7    | 0%                   | 0%                                            | 9.5 ± 3.0             |                      | Not Reported                              |
| 22. Beard 2019 unmatched | Robotic        | 272 ± 115                | 5.2%                        |                                            | Not Reported    | 9.6%                 |                                               |                       |                      |                                           |
|                          | Lap            | 253 ± 118                | 63 (12.1%)                  |                                            | Not Reported    | 32.5%                |                                               |                       |                      |                                           |
| 23. Cortillillo 2018     | Robotic        | Not Reported             |                             |                                            |                 |                      |                                               |                       |                      |                                           |
|                          | Lap            | Not Reported             |                             |                                            |                 |                      |                                               |                       |                      |                                           |
| 24. Di Sandro 2014       | Robotic        | 236 (140-360)            | 0%                          | Not Reported                               | 220 (50-450)    | Not Reported         | 0.9%                                          | 5 (IQR: 3-6)          | 0.9%                 | 7.0%                                      |
|                          | Lap            | 185 (85-310)             | NR                          | Not Reported                               | 350 (50-1,200)  | Reported             | 0.9%                                          | 4 (IQR: 2-6)          | 3.5%                 | 7.0%                                      |
| 25. Hu 2020              | Robotic        | 256.3 ± 57.7             | Not Reported                | 5.3%                                       | 319.5 ± 206.0   | 26.3%                | 0%                                            | 4.5 ± 3.8             | Not Reported         | 7.9%                                      |
|                          | Lap            | 268.4 ± 93.6             | Reported                    | 7.7%                                       | 476.9 ± 210.8   | 30.8%                | 2.1%                                          | 6.8 ± 6.0             | Not Reported         | 13.0%                                     |
| 26. Kim 2016             | Robotic        | 403.8 ± 139.0            | 0%                          | 25%                                        | 225 (125-275)   | 8.3%                 | 0%                                            | 7 (7-8)               | 8.3%                 | Not Reported                              |
|                          | Lap            | 245.9 ± 100.7            | 3.2%                        | 22.6%                                      | 150 (50-425)    | 3.2%                 | 0%                                            | 7 (5-8)               | 6.5%                 | Not Reported                              |
| 27. O'Connor 2017        | Robotic        | 216 (80-300)             | 7.7%                        | 18.0%                                      | 298 (5-1650)    | 5%                   | Not Reported                                  | 3.0 (1-9)             |                      | Not Reported                              |
|                          | Lap            | 216 (120-330)            | 28.0%                       | 34.0%                                      | 306 (5-3000)    | 6%                   | Not Reported                                  | 3.3 (1-12)            |                      | Not Reported                              |
| 28. Aziz 2021 unmatched  | Robotic        | Not Reported             |                             | 3.7%-7.3%                                  | Not Reported    |                      | 0% <sup>^^</sup>                              | 4.5 ± 3.8             | Not Reported         | 6.6% <sup>^*</sup> / 18.3% <sup>^^</sup>  |
|                          | Lap            | Not Reported             |                             | 9.8%-13.1%                                 | Not Reported    |                      | 2.2% <sup>^^</sup>                            | 6.1 ± 2.7             | Not Reported         | 12.7% <sup>^*</sup> / 26.7% <sup>^^</sup> |
| 29. Chen 2017            | Robotic        | 343 (140-715)            | 0%                          | 4.9%                                       | 282 (50-2200)   | Not Reported         | 0% <sup>^^</sup>                              | Not Reported          | 1.5%                 | 14.3% <sup>^^</sup>                       |
|                          | Lap            | 228 (83-391)             | 12.2%                       | 9.8%                                       | 191 (50-600)    | Reported             | 1.7% <sup>^^</sup>                            | 7.5 (3-26)            | 1.9%                 | 16.5% <sup>^^</sup>                       |
| 30. Han 2016             | Robotic        | Not Reported             | 0%                          |                                            |                 |                      | 0%                                            | 6.3 (2-16)            | 0%                   | Not Reported                              |
|                          | Lap            | Not Reported             | 9.6%                        |                                            |                 |                      | 0%                                            |                       | 0%                   | Not Reported                              |
| 31. Lin 2015             | Robotic        | 318.8 ± 44.1             | 0%                          | 24%                                        | 270.8 ± 161.6   | Not Reported         | 0%                                            | 7.5 ± 1.7             |                      | Not Reported                              |
|                          | Lap            | 314.6 ± 56.3             | 0%                          | 27.3%                                      | 294.6 ± 205.1   | Reported             | 0%                                            | 7.0 ± 1.3             |                      | Not Reported                              |
| 32. Lorenz 2021          | Robotic        | 330.5 ± 132.2            | Not Reported                | 19.5% <sup>**</sup>                        | 439.8 ± 346.3   | 17%                  | 0%                                            | 13.4 ± 12.5           | 4.9%                 | Not Reported                              |
|                          | Lap            | 181.3 ± 100.4            | Reported                    | 5.6% <sup>**</sup>                         | 425.4 ± 590.1   | 9.7%                 | 2.80%                                         | 8.7 ± 5.8             | 1.4%                 | Page 29 of 75                             |

| Author                                          | Study Size (N) | Operation Time (minutes) | Conversion to Open Rate (%) | Peri / Postoperative Complication Rate (%) | EBL (ml)       | Transfusion Rate (%) | Mortality Rate (%) (in-hospital, 30, 90 days) | Length of Stay (days) | Reoperation Rate (%) | Readmission Rate (%) |
|-------------------------------------------------|----------------|--------------------------|-----------------------------|--------------------------------------------|----------------|----------------------|-----------------------------------------------|-----------------------|----------------------|----------------------|
| <b>33. Magistri 2016</b>                        | Robotic        | 318 ± 113.5              | 0%                          | 100%                                       | 400 (50-1500)  | 4.5%                 | 0%                                            | 5.1 ± 2.4             | 0%                   | Not Reported         |
|                                                 | Lap            | 211 ± 78.13              | 16.7%                       | 68.2%                                      | 328 (100-1100) | 4.2%                 | 0%                                            | 6.2 ± 2.57            | 4.2%                 |                      |
| <b>34. Miller 2021</b>                          | Robotic        | 217 ± 101                | Not Reported                | Not Reported                               | Not Reported   | 10.6%                | 0.90%                                         | 4 ± 4                 | 0.9%                 | 8.80%                |
|                                                 | Lap            | 175 ± 92                 |                             |                                            |                |                      |                                               |                       |                      |                      |
| <b>35. Salloum 2017</b><br>unmatched<br>matched | Robotic        | 190 ± 87                 | 12.5%                       | 12.5%                                      | 247 ± 239      | 6.3%                 | 0%                                            | 6 ± 4                 | Not Reported         | Not Reported         |
|                                                 | Lap            | 162 ± 51                 | 2.5%                        | 11.3%                                      | 206 ± 205      | 2.5%                 | 1.30%                                         | 7 ± 8                 |                      |                      |
|                                                 | Robotic        | 203 ± 87                 | 14.3%                       | 7.1%                                       | 265 ± 253      | 7.1%                 | 0%                                            | 6 ± 3                 |                      |                      |
|                                                 | Lap            | 140 ± 33                 | 0%                          | 7.1%                                       | 121 ± 99       | 0%                   | 0%                                            | 6 ± 2                 |                      |                      |
| <b>36. Stewart 2019</b>                         | Robotic        | Not Reported             | Not Reported                | 21%                                        | Not Reported   | Not Reported         | Not Reported                                  | Not Reported          | Not Reported         | Not Reported         |
|                                                 | Lap            |                          |                             | 19%                                        |                |                      |                                               |                       |                      |                      |
| <b>37. Stiles 2017</b>                          | Robotic        | Not Reported             | 6.8%                        | Not Reported                               | Not Reported   | Not Reported         | Not Reported                                  | Not Reported          | Not Reported         | Not Reported         |
|                                                 | Lap            |                          | 20.0%                       |                                            |                |                      |                                               |                       |                      |                      |
| <b>38. Ji 2011</b>                              | Robotic        | 338 (150-720)            | 0%                          | 7.7%                                       | 280            | 0%                   | Not Reported                                  | 6.7                   | Not Reported         | Not Reported         |
|                                                 | Lap            | 130 (40-210)             | 5%                          | 10%                                        | 350            | 15%                  | Not Reported                                  | 5.2                   |                      |                      |

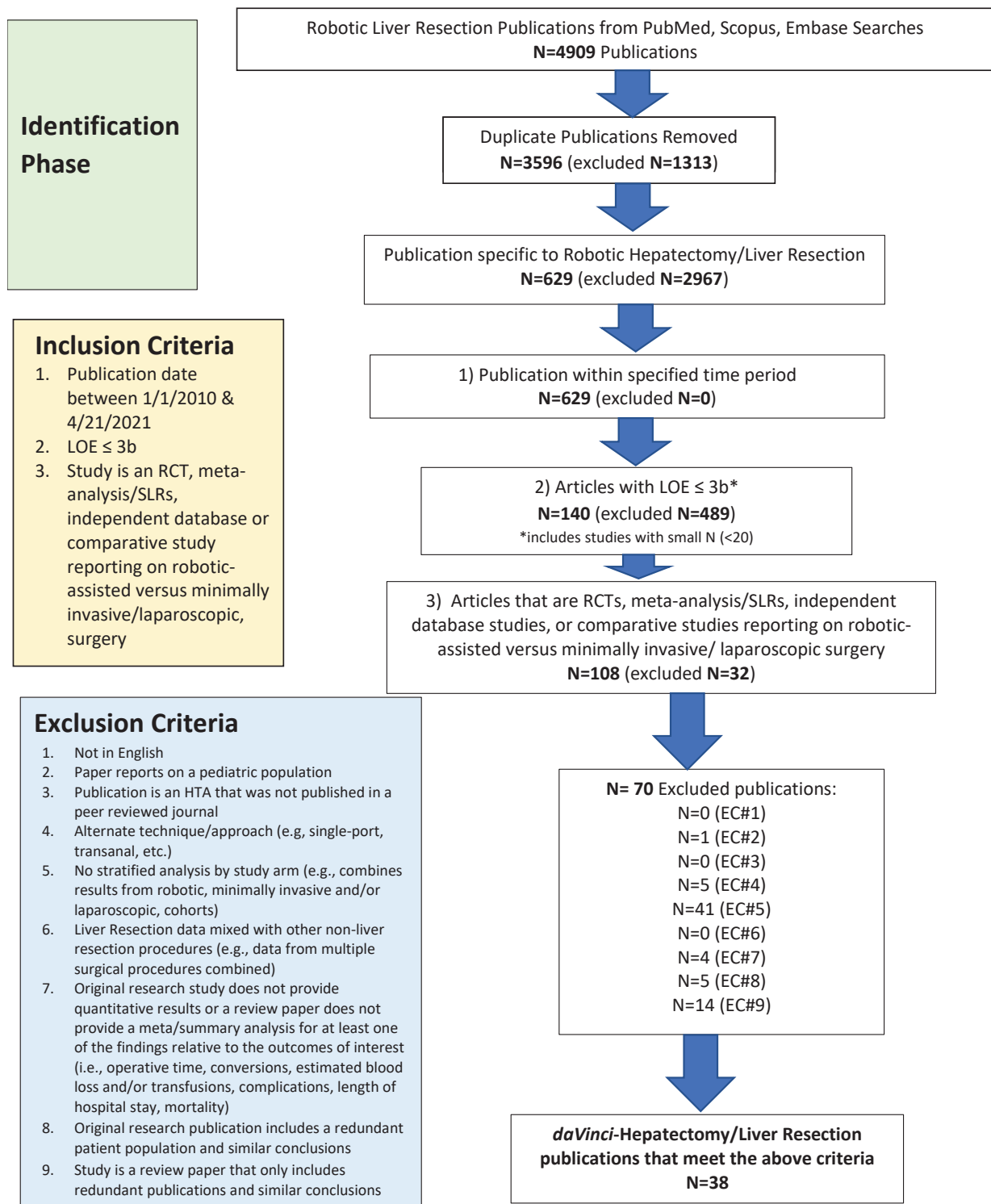
\*\*Major complications; ^90-day rate; ^^6month rate; ^^\* 45 day rate

**TABLE 1B: *da Vinci* vs. Minimally Invasive/Laparoscopic Hepatectomy/Liver Resection Procedures**

| Author                              | Study Size (N) | R0 Resection Rate (%) | PSM/R1 Resection Rate (%) | Bile leak Rate (%) | Liver failure Rate (%) |
|-------------------------------------|----------------|-----------------------|---------------------------|--------------------|------------------------|
| 1. Efanov 2017                      | Robotic        | Not Reported          | Not Reported              | 10.0%              | 0%                     |
|                                     | Lap            |                       |                           | 4.4% (bile comps)  | 1.1%                   |
| 2. Lim 2019<br>unmatched<br>matched | Robotic        | Not Reported          | 11.5%                     | Not Reported       | Not Reported           |
|                                     | Lap            |                       | 15.3%                     |                    |                        |
|                                     | Robotic        |                       | 10.9%                     |                    |                        |
|                                     | Lap            |                       | 16.4%                     |                    |                        |
| 3. Spampinato 2014                  | Robotic        | 100%                  | 0%                        | 0%                 | 0% (transient)         |
|                                     | Lap            | 91.3%                 | 8.7%                      | 8.0%               | 8% (transient)         |
| 4. Berber 2010                      | Robotic        | Not Reported          |                           |                    |                        |
|                                     | Lap            | Not Reported          |                           |                    |                        |
| 5. Chong 2019                       | Robotic        | 98.9%                 | Not Reported              |                    |                        |
|                                     | Lap            | 98.9%                 | Not Reported              |                    |                        |
| 6. Croner 2016                      | Robotic        | 100%                  | Not Reported              |                    |                        |
|                                     | Lap            | 100%                  | Not Reported              |                    |                        |
| 7. Fruscione 2019                   | Robotic        | 91.9%                 | 8.1%                      | Not Reported       |                        |
|                                     | Lap            | 92.6%                 | 7.4%                      | Not Reported       |                        |
| 8. Hu 2019                          | Robotic        | 100%                  | 0%                        | Not Reported       |                        |
|                                     | Lap            | 100%                  | 0%                        | Not Reported       |                        |
| 9. Lai 2016                         | Robotic        | 96.0%                 | Not Reported              | 2%                 | 1%                     |
|                                     | Lap            | 91.4%                 | Not Reported              | 0%                 | 0%                     |
| 10. Lee KF 2016                     | Robotic        | Not Reported          | 1.8%                      | 1.40%              | Not Reported           |
|                                     | Lap            | Not Reported          | 1.6%                      | 0%                 | Not Reported           |
| 11. Lee JS 2019                     | Robotic        | 100%                  | 0%                        | Not Reported       |                        |
|                                     | Lap            | NR                    | NR                        | Not Reported       |                        |
| 12. Marino 2018                     | Robotic        | 91.7%                 | 8.3%                      | 7.1%               | 7.1% (transient)       |
|                                     | Lap            | 85.0%                 | 10.0%                     | 10.0%              | 5% (transient)         |
| 13. Mejia 2019<br>minor<br>major    | Robotic        | Not Reported          | 9.1%                      | 0%                 | Not Reported           |
|                                     | Lap            |                       |                           | 9.4%               |                        |
|                                     | Robotic        |                       |                           | 0%                 |                        |
|                                     | Lap            |                       |                           | 25.0%              |                        |
| 14. Montali 2015                    | Robotic        | Not Reported          | 11.1%                     | 2.8%               | 5.6%                   |
|                                     | Lap            |                       | 12.5%                     | 1.4%               | 0%                     |
| 15. Packiam 2012                    | Robotic        | Not Reported          |                           |                    |                        |
|                                     | Lap            | Not Reported          |                           |                    |                        |
| 16. Tranchart 2014                  | Robotic        | Not Reported          | 7.5%                      | Not Reported       |                        |
|                                     | Lap            |                       |                           | 5.4%               | 5%                     |
| 17. Troisi 2013                     | Robotic        | Not Reported          | 5%                        | 1.3%               | Not Reported           |
|                                     | Lap            | 95%                   | 1.8% <sup>^</sup>         | Not Reported       |                        |
| 18. Tsung 2013                      | Robotic        | 92%                   | Not Reported              | 0%                 | Not Reported           |
|                                     | Lap            | 114                   | Not Reported              | 0%                 | Not Reported           |

| Author                                   | Study Size (N) | R0 Resection Rate (%) | PSM/R1 Resection Rate (%) | Bile leak Rate (%) | Liver failure Rate (%) |
|------------------------------------------|----------------|-----------------------|---------------------------|--------------------|------------------------|
| 19. Wang 2019                            | Robotic        | Not Reported          | Not Reported              | Not Reported       | Not Reported           |
|                                          | Lap            |                       |                           |                    |                        |
| 20. Wu 2014                              | Robotic        | Not Reported          | Not Reported              | 2.6%               | Not Reported           |
|                                          | Lap            |                       |                           | NR                 |                        |
| 21. Yu 2014                              | Robotic        | Not Reported          | Not Reported              | Not Reported       | Not Reported           |
|                                          | Lap            |                       |                           |                    |                        |
| 22. Beard 2019<br>matched                | Robotic        | 73.7%                 | 20.2%                     | Not Reported       | Not Reported           |
|                                          | Lap            | 77.4%                 | 20.9%                     |                    |                        |
| 23. Cortolillo 2018                      | Robotic        | Not Reported          | Not Reported              | Not Reported       | Not Reported           |
|                                          | Lap            |                       |                           |                    |                        |
| 24. Di Sandro 2014                       | Robotic        | Not Reported          | Not Reported              | 0%                 | 0%                     |
|                                          | Lap            |                       |                           | 10.0%              | 0%                     |
| 25. Hu 2020                              | Robotic        | Not Reported          | Not Reported              | Not Reported       | Not Reported           |
|                                          | Lap            |                       |                           |                    |                        |
| 26. Kim 2016                             | Robotic        | Not Reported          | Not Reported              | 8.3%               | Not Reported           |
|                                          | Lap            |                       |                           | 6.5%               |                        |
| 27. O'Connor 2017                        | Robotic        | Not Reported          | Not Reported              | Not Reported       | Not Reported           |
|                                          | Lap            |                       |                           |                    |                        |
| 28. Aziz 2021<br>matched                 | Robotic        | Not Reported          | Not Reported              | Not Reported       | 0.8%                   |
|                                          | Lap            |                       |                           |                    | 1.1%                   |
| 29. Chen 2017                            | Robotic        | Not Reported          | Not Reported              | Not Reported       | Not Reported           |
|                                          | Lap            |                       |                           |                    |                        |
| 30. Han 2016                             | Robotic        | Not Reported          | Not Reported              | Not Reported       | Not Reported           |
|                                          | Lap            |                       |                           |                    |                        |
| 31. Lin 2015                             | Robotic        | Not Reported          | Not Reported              | 4%                 | Not Reported           |
|                                          | Lap            |                       |                           | 0%                 |                        |
| 32. Lorenz 2021                          | Robotic        | Not Reported          | Not Reported              | 2.4%               | Not Reported           |
|                                          | Lap            |                       |                           | 0%                 |                        |
| 33. Magistri 2016                        | Robotic        | Not Reported          | Not Reported              | 0%                 | Not Reported           |
|                                          | Lap            |                       |                           | 4.5%               |                        |
| 34. Miller 2021                          | Robotic        | Not Reported          | Not Reported              | 4.2%               | Not Reported           |
|                                          | Lap            |                       |                           | 4.2%               |                        |
| 35. Salloum 2017<br>unmatched<br>matched | Robotic        | Not Reported          | Not Reported              | 0%                 | 0%                     |
|                                          | Lap            |                       |                           | 2.1%               | 0%                     |
| 36. Stewart 2019                         | Robotic        | Not Reported          | Not Reported              | 0%                 | Not Reported           |
|                                          | Lap            |                       |                           | 0%                 |                        |
| 37. Stiles 2017                          | Robotic        | Not Reported          | Not Reported              | Not Reported       | Not Reported           |
|                                          | Lap            |                       |                           |                    |                        |
| 38. Ji 2011                              | Robotic        | 100%                  | 0%                        | 7.7% (transient)   | Not Reported           |
|                                          | Lap            | Not Reported          | Not Reported              | 5% (transient)     |                        |

**FIGURE A: Search Criteria & Flowchart for Identification of Hepatectomy/Liver Resection Publications**



**Key Search Terms:** liver cancer, hepatocellular cancer, hepatocellular carcinoma, liver cirrhosis, hepatic/liver hemangioma, liver adenocarcinoma, liver/hepatic cyst, focal nodular hyperplasia, giant hepatic tumor, liver tumor, liver surgery, hepatic surgery, hepatic surgery, partial hepatectomy, hepatectomies, hepatectomy, segmentectomy, segmentectomies, hepatic resection, liver resection, pericystectomy, hepatic segmentectomy, hepatic sectionectomy, wedge resection, hepatic lobectomy, hepatic nodular hyperplasia, hepatic adenoma