June 11, 2025

Intuitive Surgical, Inc.
Mike Yramategui
Fellow Regulatory Engineer
1020 Kifer Road
Sunnyvale, California 94086

Re: K240852
Trade/Device Name: da Vinci X Surgical System (IS4200); da Vinci Xi Surgical System (IS4000)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: NAY
Dated: June 10, 2025
Received: June 10, 2025

Dear Mike Yramategui:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2025.06.11 14:40:48 -04'00'

Mark Trumbore 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240852

Device Name

da Vinci X Surgical System (IS4200);
da Vinci Xi Surgical System (IS4000)

Indications for Use *(Describe)*

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

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.

510(k) Summary (21 CFR § 807.92(c))

I. SUBMITTER INFORMATION

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

Contact: Mike Yramategui
Fellow Regulatory Engineer
Mike.Yramategui@intusurg.com
408-594-4207

Date Summary Prepared: June 10, 2025

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, K211784, K223080, K231224)

IV. DEVICE DESCRIPTION:

This 510(k) is for a labeling modification only, to include "tracheobronchoplasty for symptomatic, severe tracheobronchomalacia" as an additional representative, specific procedure under the previously cleared "General Thoracoscopic Surgical Procedures and Thoracoscopically-Assisted Cardiotomy Procedures" Indications for Use for 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: 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.

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 "tracheobronchoplasty for symptomatic, severe tracheobronchomalacia" as an additional representative, specific procedure under the previously cleared "General Thoracoscopic Surgical Procedures and Thoracoscopically-Assisted Cardiotomy Procedures" Indications for Use of the cleared predicate devices, *da Vinci Xi* Surgical System, Model IS4000 and the *da Vinci X* Surgical System, Model IS4200. The subject devices differ from the predicate devices by this modification to the labeling. Real world evidence (RWE) from the Premier Health Database 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.

Real World Evidence (RWE) from the Premier Health Database (PHD)

Real world evidence (RWE) from the Premier Health Database (PHD) support use of the *da Vinci Xi* and *X* Surgical Systems (Models IS4000 and IS4200) in "tracheobronchoplasty procedures" that fall under the cleared "General Thoracoscopic Surgical Procedures and Thoracoscopically-Assisted Cardiotomy Procedures" Indications for Use. Using robotic ICD/HCPCS procedure codes, robotic billing records, or a combination of both, 124 patients were identified in PHD that underwent tracheobronchoplasty procedures at 6 hospitals in the USA from 2013 to 2023.

Comparative open tracheobronchoplasty (O-TBP) data were derived from a systematic literature review. Three online databases (Embase, Scopus, and PubMed) were searched and all relevant citations were assessed against pre-defined inclusion and exclusion criteria. The key search filters applied to these publications included: 1) performance of open TBP procedures; 2) articles published between January 1,

2000 through December 31, 2023; and 3) inclusion of outcomes of interest (i.e., complications, operative time, length of stay, etc.). Three (3) publications met these criteria and were included in the analysis.[1] These publications reported on approximately 278 O-TBP procedures in patients with tracheobronchomalacia at the Massachusetts General Hospital (MGH) and the Beth Israel Deaconess Medical Center (BIDMC) from 2000 to 2023.

The results in Tables 1 – 4 demonstrated the safety and effectiveness of robotic-assisted tracheobronchoplasty surgical procedures. The findings from this analysis demonstrate that *da Vinci*-assisted procedures as compared to open procedures are substantially equivalent based on the following nine (9) outcomes of interest:

1. Operative Time
2. Conversion Rate
3. Bleeding/Transfusion Rate
4. Hospital Length of Stay
5. ICU Length of Stay
6. Complication rates
7. Mortality Rate
8. 30-Day Readmission Rate
9. 30-Day Reoperation Rate

Surgeon Experience Prior to First R-TBP Procedure

Nine (9) surgeons performing R-TBP procedures were identified in the Premier Healthcare Database between 2013 and Q1 2023. The dates that the first R-TBP procedure were performed are summarized in Table 5 for each anonymous surgeon identifier. Based on the available data from the Premier Healthcare Database, surgeons had performed the following thoracic procedures from 2016 onward[2]:

- 1 – 790 robotic-assisted thoracic procedures prior to their first R-TBP procedure.
- 0 – 337 VATS thoracic procedures prior to their first R-TBP procedure.
- 0 – 119 Open thoracic procedures prior to their first R-TBP procedure.

This real-world evidence demonstrates the safe and effective use of the *da Vinci Xi/X* systems in R-TBP procedures across a range of surgeons with varying surgical experience across robotic-assisted, VATS and open thoracic surgical procedures.

[1] 1. Buitrago, D. H., A. Majid, D. E. Alape, J. L. Wilson, M. Parikh, M. S. Kent and S. P. Gangadharan (2018). "Single-Center Experience of Tracheobronchoplasty for Tracheobronchomalacia: Perioperative Outcomes." Ann Thorac Surg 106(3): 909-915.
2. Digesu, C. S., D. Ospina-Delgado, J. Ascanio, A. Majid, M. S. Parikh, S. P. Gangadharan and J. L. Wilson (2022). "Obese Patients Undergoing Tracheobronchoplasty Have Excellent Outcomes." Ann Thorac Surg 114(3): 926-932.
3. Wright, C. D., et al. (2005). "Tracheoplasty for expiratory collapse of central airways." Ann Thorac Surg 80(1): 259-266

[2] No R-TBP procedures were identified in the Premier Healthcare Database from 2013 through 2015; thoracic experience for this assessment was evaluated from 2016 onward.

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 RWE to support the safety and effectiveness for the new labeled use of "tracheobronchoplasty" surgical procedures under the "General Thoracoscopic Surgical Procedures and Thoracoscopically-Assisted Cardiotomy Procedures" Indications for Use as compared to the predicate devices. In addition, the subject devices have the same technological characteristics as the predicate devices. Tracheobronchoplasty procedures can be completed using the *da Vinci Xi* or *X* Surgical Systems without introducing any new or different issues of safety or effectiveness as compared to the representative, specific General Thoracoscopic Surgical Procedures and Thoracoscopically-Assisted Cardiotomy surgical procedures previously cleared for the Xi and X systems. The addition of Tracheobronchoplasty as a representative, specific procedure does not represent a change or modification in the device that could significantly affect the safety or effectiveness of the device. Therefore, use of the *da Vinci Xi* and *X* Surgical Systems (Models IS4000 and IS4200) in Tracheobronchoplasty procedures are substantially equivalent to the cleared predicate devices.

Robotic and Open Tracheobronchoplasty Outcomes Data

Table 1.Demographics

Variables	Surgeon 898779703 R-TBP from PHD N=96	All Other Surgeons R-TBP from PHD N=28	Combined Surgeons R-TBP from PHD N=124	O-TBP from SLR N=278
Age in Years	66.2 (9.8)	63.5 (12.3)	65.6 (10.4)	57.4 (8.8)
Male Sex	34 (35.4)	9 (32.1)	43/124 (34.7)	94/278 (33.8)
Race				
White	76 (79.2)	20 (71.4)	96/124 (77.4)	240/264 (90.9)
Black or African American	3 (3.1)	1 (3.6)	4/124 (3.2)	Not Reported
Others	1 (1.0)	3 (10.7)	4/124 (3.2)	Not Reported
Unknown	16 (16.7)	4 (14.3)	20/124 (16.1)	Not Reported

*Unless otherwise specified, count variables are reported as Event N/Total N (Percent) and continuous variables are reported as Mean (Standard Deviation).

Table 2. Patient Comorbidities

Variables	Surgeon 898779703 R-TBP from PHD N=96	All Other Surgeons R-TBP from PHD N=28	Combined Surgeons R-TBP from PHD N=124	O-TBP from SLR
CCI, Cancer Included	1.6 (1.2)	1.4 (0.9)	1.5 (1.1)	3/103 (0.6)
Obesity	27 (28.1)	16 (57.1)	43/124 (34.7)	130/264 (49.2)
Smoking History Ever	48 (50.0)	6 (21.4)	54/124 (43.5)	144/278 (51.8)
COPD	28 (29.2)	4 (14.3)	32/124 (25.8)	103/278 (37.1)
Asthma	67 (69.8)	18 (64.3)	85/124 (68.5)	133/264 (50.4)
GERD	73 (76.0)	18 (64.3)	91/124 (73.4)	143/264 (54.2)
Obstructive Sleep Apnea	44 (45.8)	16 (57.1)	60/124 (48.4)	100/264 (37.9)
Hypertension	42 (43.8)	17 (60.7)	59/124 (47.6)	112/264 (42.4)
Diabetes	23 (24.0)	5 (17.9)	28/124 (22.6)	59/264 (22.3)
Congestive Heart Failure	6 (6.3)	2 (7.1)	8/124 (6.5)	23/264 (8.7)
Cerebrovascular Disease	1 (1.0)	0 (0.0)	1/124 (0.8)	Not Reported
Pre-operative Tracheostomy	0 (0.0)	0 (0.0)	0/124 (0.0)	19/161 (11.8)

*Unless otherwise specified, count variables are reported as Event N/Total N (Percent) and continuous variables are reported as Mean (Standard Deviation).

Table 3. Safety Outcomes

Variables	Surgeon 898779703 R-TBP from PHD N=96	All Other Surgeons R-TBP from PHD N=28	Combined Surgeons R-TBP from PHD N=124	O-TBP from SLR
Respiratory Failure	4 (4.2) [1.3, 10.6]	5 (17.9) [7.4, 36.1]	9/124 (7.3) [3.7, 13.4]	28/161 (17.4) [12.3, 24.0]
Mechanical Ventilation with Intubation	0 (0.0) [0.0, 4.6]	0 (0.0) [0.0, 14.3]	0/124 (0.0) [0, 3.6]	49/278 (17.6) [13.6, 22.6]
Prolonged Air Leak	3 (3.1) [0.7, 9.2]	0 (0.0) [0.0, 14.3]	3/124 (2.4) [0.5, 7.2]	1/161 (0.6) [0, 3.8]
Pneumothorax with Chest Tube	7 (7.3) [3.3, 14.5]	1 (3.6) [0.0, 19.2]	8/124 (6.5) [3.1, 12.4]	6/264 (2.3) [0.9, 5.0]
Pleural Effusion	2 (2.1) [0.1, 7.7]	0 (0.0) [0.0, 14.3]	2/124 (1.6) [0.1, 6.1]	8/264 (3.0) [1.4, 6.0]
Chest Tube After Surgery	4 (4.2) [1.3, 10.6]	0 (0.0) [0.0, 14.3]	4/124 (3.2) [1.0, 8.3]	Not Reported
Hemothorax	1 (1.0) [0.0, 6.2]	0 (0.0) [0.0, 14.3]	1/124 (0.8) [0, 4.9]	Not Reported
Intraoperative Bleeding**	0 (0.0) [0.0, 4.6]	0 (0.0) [0.0, 14.3]	0/124 (0.0) [0, 3.6]	N = 161 200 (111.1) [182.8, 217.2]
Postprocedural Bleeding	1 (1.0) [0.0, 6.2]	0 (0.0) [0.0, 14.3]	1/124 (0.8) [0, 4.9]	3/264 (1.1) [0.2, 3.4]
Venous Thromboembolism	0 (0.0) [0.0, 4.6]	0 (0.0) [0.0, 14.3]	0/124 (0.0) [0, 3.6]	7/264 (2.7) [1.2, 5.5]
Surgical Site Infection	0 (0.0) [0.0, 4.6]	0 (0.0) [0.0, 14.3]	0/124 (0.0) [0, 3.6]	9/264 (3.4) [1.7, 6.4]
Bronchitis	4 (4.2) [1.3, 10.6]	1 (3.6) [0.0, 19.2]	5/124 (4.0) [1.5, 9.3]	5/264 (1.9) [0.7, 4.5]
Pneumonia	1 (1.0) [0.0, 6.2]	1 (3.6) [0.0, 19.2]	2/124 (1.6) [0.1, 6.1]	39/278 (14.0) [10.4, 18.6]
Atrial Arrhythmia	4 (4.2) [1.3, 10.6]	0 (0.0) [0.0, 14.3]	4/124 (3.2) [1.0, 8.3]	17/264 (6.4) [4.0, 10.1]
Acute Renal Failure	1 (1.0) [0.0, 6.2]	2 (7.1) [0.9, 23.7]	3/124 (2.4) [0.5, 7.2]	30/264 (11.4) [8.0, 15.8]
Injury to Adjacent Organs	0 (0.0) [0.0, 4.6]	1 (3.6) [0.0, 19.2]	1/124 (0.8) [0, 4.9]	Not Reported
Mortality, N (%)	0 (0.0) [0.0, 4.6]	0 (0.0) [0.0, 14.3]	0/124 (0.0) [0, 3.6]	2/278 (0.7) [0, 2.8]
30-Day Readmission	7 (7.3) [3.3, 14.5]	4 (14.3) [5.1, 32.1]	11/124 (8.9) [4.9, 15.3]	19/161 (11.8) [7.6, 17.8]
30-Day Reoperation	1 (1.0) [0.0, 6.2]	1 (3.6) [0.0, 19.2]	2/124 (1.6) [0.1, 6.1]	4/161 (2.5) [0.8, 6.4]

*Unless otherwise specified, count variables are reported as Event N/Total N (Percent) [Lower 95% CI, Upper 95% CI] and continuous variables are reported as Mean (Standard Deviation) [Lower 95% CI, Upper 95% CI]. 95% confidence intervals are calculated for continuous outcomes and 95% Agresti-Coull confidence intervals are calculated for categorical outcomes.

**All identified O-TBP papers reported intraoperative bleeding as mL blood loss. The data used for the R-TBP cohort does not report mL blood loss, and so ICD-9/10 codes and CPT codes were used to identify whether or not blood loss was reported during the procedure.

Table 4. Effectiveness Outcomes

Variables	Surgeon 898779703 R-TBP from PHD N=96	All Other Surgeons R-TBP from PHD N=28	Combined Surgeons R-TBP from PHD N=124	O-TBP from SLR
Surgical Time in Minutes	325.0 (53.8) [314.1, 335.9]	343.4 (83.0) [311.2, 375.6]	329.1 (61.7) [318.2, 340.1]	N = 264 388.2 (60.2) [381.0, 395.5]
Hospital Length of Stay in Days	4.1 (3.2) [3.5, 4.8]	5.1 (5.8) [2.9, 7.4]	4.4 (3.9) [3.7, 5.1]	N = 175 8.1 (3.7) [7.5, 8.6]
ICU Length of Stay in Days	1.7 (1.8) [1.4, 2.1]	1.9 (3.5) [0.6, 3.3]	1.8 (2.3) [1.4, 2.2]	N = 264 3.7 (1.2) [3.6, 3.9]
Conversion to Open Surgery	0 (0.0) [0.0, 4.6]	1 (3.6) [0.0, 19.2]	1 (0.8) [0, 4.9]	Not Applicable
Discharge Disposition**				
Home or Self Care	71 (74.0) [64.3, 81.7]	16 (57.1) [39.1, 73.5]	87/124 (70.2) [61.6, 77.5]	60/161 (37.3) [30.2, 45.0]
Home with Assistance	24 (25.0) [17.4, 34.6]	11 (39.2) [23.5, 57.6]	35/124 (28.2) [21.0, 36.7]	50/161 (31.1) [24.4, 38.6]
Rehabilitation Facility	1 (1.0) [0.0, 6.2]	1 (3.6) [0.0, 19.2]	2/124 (1.6) [0.1, 6.1]	49/161 (30.4) [23.8, 37.9]

*Unless otherwise specified, count variables are reported as Event N/Total N (Percent) [Lower 95% CI, Upper 95% CI] and continuous variables are reported as Mean (Standard Deviation) [Lower 95% CI, Upper 95% CI]. 95% confidence intervals are calculated for continuous outcomes and 95% Agresti-Coull confidence intervals are calculated for categorical outcomes.

**For the R-TBP cohort discharge disposition, “Home with Assistance” includes the categories “Home Health Organization” (n = 34, 27.4%) and “Skilled Nursing Facility” (n = 1, 0.8%).

TABLE 5: Thoracic Surgical Procedure Experience Prior to First R-TBP Procedure

De-Identified Surgeon ID**	Date of First R-TBP	RAS TBP Procedures performed in the Study	Number of Thoracic Procedures* BEFORE first R-TBP		
			RAS	VATS	Open
2156970	**2/10/2023**	1	131	337	119
6084487	**9/15/2020**	1	1	3	0
11945750	**7/13/2022**	1	790	14	5
26035138	**2/18/2020**	7	93	9	1
27087862	**1/26/2022**	8	699	167	36
27218818	**6/13/2017**	8	15	21	2
86160552	**3/25/2022**	1	34	0	0
119279619	**11/1/2022**	1	12	0	1
898779703	**9/12/2016**	96	74	19	5
		Grand Total =	**1,849**	**570**	**169**

* Thoracic procedures identified using ICD-10 PCS codes from the Healthcare Cost Utilization Project CCSR category RES008 (Lung, pleura, or diaphragm resection).

** Surgeons who performed their first TBP earlier in the range of available data had less available information to ascertain thoracic surgery experience.