February 10, 2021

Intuitive Surgical, Inc.
Kunal Gunjal
Sr. Regulatory Affairs Specialist
1266 Kifer Road, Building 101
Sunnyvale, California 94086

Re: K203632
Trade/Device Name: da Vinci S/Si (IS2000/IS3000) 5mm and 8mm Reusable Instruments, da Vinci Xi/X (IS4000/IS4200) 8mm Reusable Instruments
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NAY, GCJ
Dated: December 10, 2020
Received: December 11, 2020

Dear Kunal Gunjal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Je Hi An, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203632

Device Name
da Vinci S/Si (IS2000/IS3000) EndoWrist Instruments (5mm and 8mm)

Indications for Use *(Describe)*
The Intuitive Surgical Endoscopic Instrument Control System is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, ultrasonic shears, forceps/pick-ups, needle holders, endoscopic retractors, stabilizers, 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, transoral otolaryngology surgical procedures restricted to benign and malignant tumors classified as TI and T2, and for benign base of tongue resection 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 (except for transoral otolaryngology surgical procedures). 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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FORM FDA 3881 (7/17) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203632

Device Name

da Vinci Xi (IS4000) 8mm Instruments

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 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)*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203632

Device Name
da Vinci X (IS4200) 8mm Instruments

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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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FORM FDA 3881 (7/17) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

Table 1: *da Vinci S/Si* (IS2000/IS3000) Reusable Instruments

510(k) Owner	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086
Contact	Kunal Gunjal Sr. Regulatory Affairs Specialist, Regulatory Affairs Phone Number: 408-523-8017 Email: Kunal.Gunjal@intusurg.com
Trade Name	*da Vinci S/ Si* (IS2000/IS3000) *EndoWrist* Instruments (5mm & 8mm)
Common Name	Endoscope and accessories
Classification	Class II, 21 CFR 876.1500
Product Codes	NAY
Review Panel	General and Plastic Surgery
Predicate Devices	K170644 (Clearance of Reprocessing Instructions for *da Vinci S and Si* Reusable Instruments)

Table 2: *da Vinci X/Xi (IS4200/IS4000)* 8mm Reusable Instruments

510(k) Owner	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086
Contact	Kunal Gunjal Sr. Regulatory Affairs Specialist, Regulatory Affairs Phone Number: 408-523-8017 Email: Kunal.Gunjal@intusurg.com
Trade Name	*da Vinci Xi/X* (IS4000/IS4200) 8mm Reusable Instruments
Common Name	Endoscope and accessories
Classification	Class II, 21 CFR 876.1500
Product Codes	NAY, GCJ
Review Panel	General and Plastic Surgery
Predicate Devices	K170645 (Clearance of Reprocessing Instructions for *da Vinci Xi 8mm Reusable* Instruments)

Device Description

Table 3 lists the device descriptions for the subject devices impacted by the changes to the reprocessing instructions.

Table 3: *da Vinci S/Si and X/Xi* Reusable Instruments

Trade Name	*da Vinci S/ Si* (IS2000/IS3000) *EndoWrist* Instruments (5mm & 8mm)	*da Vinci Xi/X* (IS4000/IS4200) Reusable Instruments (8mm)
Device Description	*da Vinci S/ Si* (IS2000/IS3000) *EndoWrist* Instruments have a unique articulating design at their distal tips that mimics the human wrist. While seated at the Surgeon Console of the Surgical System, the surgeon can precisely control movements of the end effectors/instrument tips to perform one or more specific surgical tasks e.g., grasping, suturing, cutting, cauterizing, or tissue manipulation.	The *da Vinci X/Xi* (IS4200/IS4000) *EndoWrist* Instruments have a unique articulating design at their distal tips that mimics the human wrist. While seated at the Surgeon Console of the Surgical System, the surgeon can precisely control movements of the end effectors/instrument tips to perform one or more specific surgical tasks e.g., grasping, suturing, cutting, cauterizing, or tissue manipulation.

Indications for Use:

Table 4 lists the Indications for Use for the devices impacted by the changes to the reprocessing instructions.

Table 4: *da Vinci S/Si and X/Xi* Reusable Instruments

Trade Name	*da Vinci S/ Si* (IS2000/IS3000) *EndoWrist* Instruments (5mm & 8mm)	*da Vinci Xi* (IS4000) 8mm Reusable Instruments	*da Vinci X* (IS4200) 8mm Reusable Instruments
Indications for Use	The Intuitive Surgical Endoscopic Instrument Control System is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, ultrasonic shears, forceps/pick-ups, needle holders, endoscopic retractors, stabilizers, 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, transoral otolaryngology surgical procedures restricted to benign and malignant tumors classified as TI and T2, and for benign base of tongue resection 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 (except for transoral otolaryngology surgical procedures). 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.	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 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.	The Intuitive Surgical Endoscopic Instrument Control System (*da Vinci X* Surgical System, Model IS4200) is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps/pick-ups, needle holders, endoscopic retractors, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, and delivery and placement of microwave and cryogenic ablation probes and accessories, during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general thoracoscopic surgical procedures and thoracoscopically-assisted cardiotomy procedures. The system can also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. The system is indicated for adult and pediatric use. It is intended to be used by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

Table 5 and Table 6 includes a comparison between the subject devices and predicate devices.

Table 5: Comparison of Predicate and Subject Devices (*da Vinci S/Si EndoWrist 5mm and 8mm instruments*)

Characteristic	**Subject Device** *da Vinci* IS2000/IS3000 *5mm and 8mm Instruments* (K203632)	**Predicate Device** *da Vinci* IS2000/IS3000 *5mm and 8mm Instruments* (K170644)
Manufacturer	Intuitive Surgical, Inc.	Intuitive Surgical, Inc.
Trade Name	*da Vinci S/Si (*IS2000/IS3000) 5mm/8mm instruments	**SAME** as subject device
Common Name	Endoscope and accessories	**SAME** as subject device
Regulation No.	21 CFR 876.1500	**SAME** as subject device
Product Code	NAY	**SAME** as subject device
Device Class/ Regulation Name	Class II	**SAME** as subject device
Classification Advisory Committee	General and Plastic Surgery	**SAME** as subject device

Characteristic	**Subject Device** *da Vinci* IS2000/IS3000 *5mm and 8mm Instruments* (K203632)	**Predicate Device** *da Vinci* IS2000/IS3000 *5mm and 8mm Instruments* (K170644)
Indications for Use	The *Intuitive Surgical* Endoscopic Instrument Control System is intended to assist in the accurate control of *Intuitive Surgical* Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, ultrasonic shears, forceps/pick-ups, needle holders, endoscopic retractors, stabilizers, 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, transoral otolaryngology surgical procedures restricted to benign and malignant tumors classified as TI and T2, and for benign base of tongue resection 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 (except for transoral otolaryngology surgical procedures). 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.	**SAME** as subject device
Prescription use	Physician use only	**SAME** as subject device

Characteristic	**Subject Device** *da Vinci* IS2000/IS3000 *5mm and 8mm Instruments* (K203632)	**Predicate Device** *da Vinci* IS2000/IS3000 *5mm and 8mm Instruments* (K170644)
Where used (hospital, home, ambulance, etc)	Hospital	**SAME** as subject device
Sterilization Method	Steam sterilization	**SAME** as subject device
Sterility / Disposable or Multiple use	Multiple use	**SAME** as subject device
Reprocessing Instructions	Reprocessing Instructions have been updated to include an optional automated cleaning and disinfection process using an automated washer/disinfector.	Reprocessing Instructions include a ***manual cleaning process*** using an ultrasonic bath. Reprocessing Instructions include ***thermal disinfection parameters***.
Packaging	Non-sterile packaging, reusable	**SAME** as subject device

Table 6: Comparison of Predicate and Subject Devices (*da Vinci X/Xi EndoWrist 8mm* Instruments)

Characteristic	**Subject Device** *da Vinci X/Xi (IS4200/IS4000) EndoWrist (8mm)* Instruments (K203632)	**Predicate Device** *da Vinci Xi (IS4000) EndoWrist (8mm)* Instruments (K170645)
Manufacturer	Intuitive Surgical, Inc.	Intuitive Surgical, Inc.
Trade Name	*da Vinci X/Xi EndoWrist* (8mm) Instruments	*da Vinci Xi EndoWrist* (8mm) Instruments
Common Name	Endoscope and accessories	**SAME** as subject device
Regulation No.	21 CFR 876.1500	**SAME** as subject device
Product Code	NAY, GCJ	**SAME** as subject device
Device Class/ Regulation Name	Class II	**SAME** as subject device
Classification Advisory Committee	General and Plastic Surgery	**SAME** as subject device

Characteristic	**Subject Device** *da Vinci X/Xi (IS4200/IS4000) EndoWrist (8mm)* Instruments (K203632)	**Predicate Device** *da Vinci Xi (IS4000) EndoWrist (8mm)* Instruments (K170645)
Indications for Use for *da Vinci Xi (IS4000)* EndoWrist 8mm Instruments	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 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.	**SAME** as subject device

Characteristic	**Subject Device** *da Vinci X/Xi (IS4200/IS4000) EndoWrist (8mm)* Instruments (K203632)	**Predicate Device** *da Vinci Xi (IS4000) EndoWrist (8mm)* Instruments (K170645)
Indications for Use for *da Vinci X* (IS4200) *EndoWrist* 8mm Instruments **NOTE: The same *da Vinci EndoWrist* 8mm instruments are used with the *da Vinci X* (IS4200) system and *da Vinci Xi* (IS4000) system**	The Intuitive Surgical Endoscopic Instrument Control System (da Vinci X Surgical System, Model IS4200) is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps/pick-ups, needle holders, endoscopic retractors, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, and delivery and placement of microwave and cryogenic ablation probes and accessories, during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general thoracoscopic surgical procedures and thoracoscopically-assisted cardiotomy procedures. The system can also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. The system is indicated for adult and pediatric use. It is intended to be used by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.	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 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.

Characteristic	**Subject Device** *da Vinci X/Xi (IS4200/IS4000) EndoWrist (8mm)* Instruments (K203632)	**Predicate Device** *da Vinci Xi (IS4000) EndoWrist (8mm)* Instruments (K170645)
Prescription use	Physician use only	**SAME** as subject device
Where used (hospital, home, ambulance, etc)	Hospital	**SAME** as subject device
Sterilization Method	Steam sterilization	**SAME** as subject device
Sterility / Disposable or Multiple use	Multiple use	**SAME** as subject device
Reprocessing Instructions	Reprocessing Instructions have been updated to include an optional automated cleaning and disinfection process using an automated washer/disinfector.	Reprocessing Instructions include a ***manual cleaning process*** using an ultrasonic bath. Reprocessing Instructions include ***thermal disinfection parameters***.
Packaging	Non-sterile packaging, reusable	**SAME** as subject device

Technological Characteristics:

There were no changes to design including technological characteristics for the subject devices as a result of the reprocessing instructions changes to include use of an automated washer/disinfector.

Performance Data:

Performance test data demonstrates that the subject device is substantially equivalent to the predicate device. The testing conducted consisted of Cleaning Validation, Thermal Disinfection validation, Reliability/Life Testing and Human factors testing.

- **Cleaning Validation**: Cleaning Validation was performed to validate the efficacy of the automated cleaning process using an automated washer-disinfector in accordance with the following standards and guidance documents:

  - FDA Guidance, *"Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling"*, document issued on: March 17, 2015
  - AAMI TIR 12:2010 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
  - AAMI TIR 30: 2011/(R)2016, A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
  - ANSI/AAMI ST15883-1:2009/(R) 2014, Washer-disinfectors: General requirements, terms and definitions and tests

  The *da Vinci S/Si and X/Xi* Reusable Instruments successfully met the acceptance criteria for all markers. The test results demonstrate that the *da Vinci S/Si and X/Xi* Reusable Instruments can be cleaned using an automated washer/disinfector.

- **Thermal Disinfection Validation**: Efficacy of the thermal disinfection process was validated for the subject devices per the FDA Guidance, "*Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors; Guidance for the Medical Device Industry and FDA Review Staff*", Document Issued on February 7, 2002. The subject devices meet the acceptance criteria which validates the efficacy of the thermal disinfection cycle within the automated washer/disinfector.

- **Reliability/Life Testing**: Reliability/Life Testing was performed to ensure that *da Vinci* instruments are not adversely affected by the use of an automated washer-disinfector for reprocessing these instruments. The subject devices within the scope of this submission meet the acceptance criteria.

- **Human Factors Testing**: The Reprocessing Instructions underwent a rigorous Human Factors Testing process. This process included:
  - Preliminary Evaluation: A preliminary evaluation was completed to better understand the users, uses, and use environment.
  - Usability Risk Analysis (URA): Task and Use Error analysis was conducted for Reprocessing. This analysis included the process and Reprocessing Instructions.
  - Design Team Participation: Human Factors Engineers participated in design meetings and played a significant role in the visual design and content development.

- Formative Testing: Formative tests were completed during the development of the new Reprocessing Instructions.
- Validation Testing: Validation test of representative Reprocessing Instructions was completed with representative end users.

This validation study assessed the usability, effectiveness, and use safety of the Reprocessing Instructions.

Summary:

Based on the intended use, indications for use, technological characteristics and performance data, the subject device is substantially equivalent to the predicate devices listed in **Table 1 and Table 2.**