DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 26, 2014

Intuitive Surgical Incorporated
Ms. Einav Yemini
Associate Regulatory Engineer
1266 Kifer Road
Sunnyvale, California 94086

Re: K141075
Trade/Device Name: *Single-Site*™ Wristed Needle Driver
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NAY
Dated: August 22, 2014
Received: August 27, 2014

Dear Ms. Yemini:

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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Precautions/Warnings/Contraindications section of the device's labeling:

The safety and effectiveness of this device for use in the performance of general laparoscopic abdominal surgery or general gynecological surgery procedures have not been established. This device is only intended to be used for single incision laparoscopic cholecystectomy, benign hysterectomy, and salpingo-oophorectomy with the da Vinci Single Site Instruments and the da Vinci Si Surgical System (IS3000).

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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 [SELECT ONE: Part 801 [OR, for IVDs only] Parts 801 and 809]); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

William H. Maisel -S

William H. Maisel, MD, MPH
Director, Office of Device Evaluation (Acting)
Deputy Center Director for Science
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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
Not known. To be assigned.

Device Name
Single-Site® Wristed Needle Driver

Indications for Use *(Describe)*
The Intuitive Surgical® da Vinci® Single-Site™ Instruments and Accessories used with the da Vinci® Si Surgical System (IS3000) are indicated for use by trained physicians in an operating room environment for endoscopic manipulation of tissue, grasping, cutting, blunt and sharp dissection, approximation, clip-ligation, electrocautery and suturing during single incision laparoscopic cholecystectomy, benign hysterectomy and salpingo-oophorectomy with the da Vinci Single-Site Instruments and Accessories, including graspers, dissectors, needle drivers, scissors, suction irrigators, monopolar cautery, bipolar cautery, 5 mm curved cannulae, 5 mm and 10 mm straight cannulae, flexible blunt obturators, and the Single-Site Port.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Office of Chief Information Officer
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
[As Required by 21 CFR 807.92(c)]

510(k) Owner: Intuitive Surgical, Inc.
1266 Kifer Road
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Official Contact: Einav Yemini
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Date Summary Prepared: August 22, 2014

Trade Name: *Single-Site*™ Wristed Needle Driver

Common Name: Endoscope and accessories

Product Code: NAY

Classification: Class II

Endoscope and Accessories, 21 CFR 876.1500

Classification Advisory Committee: General and Plastic Surgery

Predicate Device(s): *Single-Site*™ Curved Needle Driver (K122532)

Device Description:

The *da Vinci*® *Single-Site*™ Instruments and Accessories consist of semi-rigid shaft instruments, two fixed-shape curved cannulae sets (250 mm and 300 mm lengths), an accessory cannula for insertion of manual laparoscopic instruments, semi-rigid blunt obturators (250 mm and 300 mm lengths), a rigid 10 mm Blunt Obturator, and a *Single-Site*™ Port (with insufflation adapter and stopcock) for the placement and insertion of multiple cannulae/instruments through a single incision.

The *da Vinci*® *Single-Site*™ Instruments and Accessories include instruments to perform manipulation of tissue, grasping, cutting, blunt and sharp dissection, approximation, clip-ligation, electrocautery, and suturing. The *da Vinci*® *Single-Site*™ Instruments and Accessories are intended to be used with the existing *da Vinci*® *Si*™ Surgical System (IS3000).

The subject device, *Single-Site*™ Wristed Needle Driver (P/N 428115), is a new addition to the *Single-Site*™ Instruments and Accessories family. It is a resposable endoscopic instrument used in conjunction with the *da Vinci*® *Si*™ Surgical System (IS3000) to handle needles and suture during endoscopic surgical procedures. The distal end configuration of the instrument includes a straight grip and a wrist to enable articulation of the grip.

Intended Use:

The *Single-Site*™ Wristed Needle Driver instrument is intended to be used with the *da Vinci*® *Si*™ Surgical System (IS3000) to perform needle driving and suture tying tasks.

Indications for Use

The *Intuitive Surgical*® *da Vinci*® *Single-Site*™ Instruments and Accessories used with the *da Vinci*® *Si*™ Surgical System (IS3000) are indicated for use by trained physicians in an operating room environment for endoscopic manipulation of tissue, grasping, cutting, blunt and sharp dissection, approximation, clip-ligation, electrocautery, and suturing during single incision laparoscopic cholecystectomy, benign hysterectomy and salpingo-oophorectomy with the *da Vinci Single-Site* Instruments and Accessories, including graspers, dissectors, needle drivers, scissors, suction irrigators, monopolar cautery, bipolar cautery, 5 mm curved cannulae, 5 mm and 10 mm straight cannulae, flexible blunt obturators, and the *Single-Site*™ Port.

The indications for use are unchanged from the predicate (K122532).

Technological Characteristics

The *Single-Site*™ Wristed Needle Driver instrument is substantially equivalent to the cleared *Single-Site*™ Curved Needle Driver (K122532). The design of the *Single-Site*™ Wristed Needle Driver is a modification of the *da Vinci*® *Single-Site*™ Curved Needle Driver (K122532) to incorporate a wrist at the distal end of the instrument. The wrist provides additional range of motion and facilitates suturing tasks. Additionally, the grip configuration was revised from a curved to a straight grip. The *Single-Site*™ Wristed Needle Driver is equivalent to the predicate *Single-Site*™ Curved Needle Driver in terms of its technological characteristics, and the intended use is identical.

Performance Data

Performance data (bench, animal and cadaver testing) demonstrate that the subject device is substantially equivalent to the predicate device and that the design output meets the design input requirements. The tests included dimensional measurements, mechanical and functional verification, and simulated use in animal and cadaver models as follow.

Bench Verification

The *Single-Site*™ Wristed Needle Driver instrument was subjected to design verification and reliability (life) testing to evaluate performance and demonstrate that the design output meets design input requirements. The tables below provide a summary of the bench verification testing.

Design Verification Testing

Category	Description
Purpose / Scope	Verification that the design of the instrument meets its physical, mechanical, electrical, user interface, and equipment interface requirements.
# of Test Samples	Five (5)
Models	Bench Testing
Test Methodology	Physical measurements, verification of mechanical requirements, functional performance requirements, electrical requirements, user interface requirements, and equipment interface requirements.

Reliability (life) Testing

Category	Description
Purpose / Scope	Testing to demonstrate that the instrument will operate properly throughout its intended life of five uses.
# of Test Samples	Eight
Models	Bench testing
Test Methodology	Instruments are subjected to repeated cycles of simulated life, including cleaning, sterilization, and simulated surgical tasks that mimic actual maneuvers performed during minimally invasive surgical operations. Performance requirements are evaluated during each cycle and more extensive mechanical measurements are done at cycles #1, #5, and #7, to confirm performance remains within specification.

Cadaver and Animal Validations

A cadaver model was used to demonstrate clinical performance for anatomical access and reach. A live animal model was used to assess safety and performance in cases where a live tissue model was appropriate. The live animal model replicates factors experienced during clinical use, including working with perfused organs, bleeding, normal tissue handling, and ensure that appropriate hemostasis is achieved and maintained.

For design validation, the cadaver model allowed evaluation of vaginal cuff closure, and a live porcine model allowed evaluation of suturing live tissue that is representative of dense muscular tissue, similar to the vaginal cuff. The table below provides a summary of the design validation testing.

Design Validation Testing

Category	Description
Purpose / Scope	Confirm that instrument meets product requirements, specifications, and user needs
# of Test Samples	Two (2)
Models Used	Cadaver (3) and animal (2)
Test Methodology	Utilize instrument in representative uses to confirm that device meets general clinical use requirements, performance, functionality, compatibility, and user-related requirements

For equivalency testing, five (5) independent practicing surgeons participated in a study completing a comprehensive set of suturing tasks using both the *Single-Site*™ Wristed Needle Driver (subject) and the *Single-Site*™ Curved Needle Driver (predicate). With each instrument, each surgeon completed at least two gynecologic suturing tasks in cadaver models and three gynecologic suturing tasks in porcine models, for a total of 52 completed suturing tasks with both instruments. Surgeons completed questionnaires that evaluated the suturing performance, suture line quality, and safety with the each needle driver; study observers recorded objective assessments of the suture lines quality. The tables below provide a summary of the equivalence testing.

Equivalence Testing – Cadaver

Category	Description
Purpose / Scope	Demonstrate substantial equivalence of addition of a wrist to the needle driver instrument (*Single-Site* Wristed Needle Driver).
Comparison Device(s)	*Single-Site* Curved Needle Driver
Models used / Evaluation areas	The ability to perform a complete procedure (benign hysterectomy with bilateral salpingo-oophorectomy) was evaluated using a cadaver model. Cadavers were used to represent human anatomy and size, and to confirm that the instrument can adequately access the necessary structures and perform the complete procedure. Comparison of the safety and performance of the applicable needle driver to the comparative device was done as follows: • Ability to perform a vaginal cuff closure in a cadaver model.
Evaluators / Number of Evaluators	5 independent surgeons (5 cadavers)
Procedures / Tasks evaluated	Full Procedures: Benign hysterectomy with bilateral salpingo- oophorectomy (n=5) Cadaver suturing task: Vaginal cuff closure (n=11)
Procedure Completion	Confirmation that surgeon was able to complete full procedure
Suture Line Quality and Effectiveness	Likert Scale and yes/no questions used to compare surgeons visual assessment of quality and effectiveness of the suture lines. Intraoperative measurements: • Tissue Bite • Number of stitches • Distance between stitches • Closure completion time
Suturing Task Elements	Likert Scale used to compare the ability to perform suturing tasks.
Ease of Use	Subjective surgeon assessment of ability to perform task/procedure
Safety Assessments	Study observer, surgeon participant, and independent reviewer assessments • Ability to operate safely • Any instances of harm

Equivalence Testing – Animal

Category	Description
Purpose / Scope	Demonstrate substantial equivalence of addition of a wrist to the needle driver instrument (*Single-Site* Wristed Needle Driver).
Comparison Device(s)	*Single-Site* Curved Needle Driver
Models used / Evaluation areas	Comparison of the safety and performance of the applicable needle driver to the comparative device was done as follows: • Ability to perform applicable suturing tasks in a live porcine model. Live animals (porcine) were used to represent the effects of live tissue during clinical use and compare performance and safety for representative suturing tasks.
Evaluators / Number of Evaluators	5 independent surgeons (5 animals)
Procedures / Tasks evaluated	Porcine suturing task: Uterine horn hysterotomy closure (n=15, 3/surgeon)
Suture Line Quality and Effectiveness	Surgeon's assessment (yes/no) and Likert Scale questions used to compare quality and effectiveness of the suture lines. Intraoperative measurements: • Tissue Bite • Number of stitches • Distance between stitches • Closure completion time
Suturing Task Elements	Likert Scale used to compare the ability to perform suturing tasks.
Ease of Use	Subjective surgeon assessment of ability to perform task/procedure
Safety Assessments	Study observer, surgeon participant, and independent reviewer assessments • Ability to operate safely • Any instances of harm

Clinical Evaluation

No clinical testing was provided with this submission using the subject device. Safety, effectiveness and substantial equivalence were demonstrated through bench testing, cadaver and animal validations, and comparison testing, performed with the subject device. The testing performed demonstrated that:

- The device can perform its intended function
- The device can perform the surgical tasks proposed in the Indications for Use safely and effectively
- The clinical performance and safety of the device is equivalent to the predicate device

Human Factors Evaluation

Risk analysis was performed for Human Factors. No human factors testing was provided with this submission using the subject device. The device does not include any new user interfaces and does not present any new usability risks compared to the predicate.

Conclusion

Based on the intended use, indications for use, technological characteristics, and performance data, the *Single-Site*™ Wristed Needle Driver is substantially equivalent (SE) to the predicate device. This SE determination is based on bench testing including reliability testing, animal/cadaver validation, simulated clinical procedures in live animals, and human factors assessment. The bench/reliability testing verified that the design requirements and specifications for the new and/or changed components of the instrument were met. The animal and cadaver validation demonstrated the users' ability to use the system to accurately control the instrument, to reach the necessary target anatomy, and to perform the surgical task. The simulated clinical procedures in cadavers and live animals provided clinical validation that the instrument can safely and effectively complete surgical tasks in procedure steps encompassed by the Indications for Use statement.