



Food and Drug Administration
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September 17, 2014

Intuitive Surgical Inc.
c/o Cindy Domecus, R.A.C.
Principal, Domecus Consulting Services LLC
1020 Kifer Road
Sunnyvale, California 94086

Re: K123329

Trade/Device Name: Intuitive Surgical *da Vinci*[®], *da Vinci S*[®], and *da Vinci Si*[®] Surgical Systems and *EndoWrist* Instruments and Accessories
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NAY
Dated: February 11, 2014
Received: February 12, 2014

Dear Ms. Domecus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). 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 Warnings section of the device's labeling:

The safety and effectiveness of this device for use in the treatment of obstructive sleep apnea have not been established.

Furthermore, the indication for use must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

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

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

Indications for Use

510(k) Number (if known)
K123329

Device Name
Intuitive Surgical® da Vinci®, da Vinci S® and da Vinci Si® Surgical Systems and EndoWrist Instruments and Accessories

Indications for Use (Describe)
Transoral otolaryngology surgical procedures restricted to benign and malignant tumors, classified as T1 and T2, and for benign base of tongue resection procedures.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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 (21 CFR § 807.92(c))

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Date Summary Prepared: September 17, 2014

Device Trade Name: Intuitive Surgical® *da Vinci*®, *da Vinci S*® and *da Vinci Si*® Surgical Systems and *EndoWrist* Instruments and Accessories

Common Name: Endoscopic Instrument Control System, Endoscopic Instruments and Accessories

Classification Name: Endoscope and Accessories (21 CFR §876.1500)

Product Code: NAY, System, Surgical, Computer Controlled Instrument

Equivalent Devices: Intuitive Surgical *da Vinci* Surgical Systems (Models IS1200, IS2000, IS3000) and *EndoWrist* Instruments and Accessories legally marketed under: K990144, K002489, K011002, K011281, K012833, K013416, K021036, K022574, K040237, K040948, K042855, K043153, K043288, K050005, K050369, K050404, K050802, K060391, K061260, K063220, K081137, K090993, K093217, K101743, K101581, K110451, K112584, K112263, and K110639

Device Description:

This 510(k) is being submitted for a revision to the Indications for Use to include Transoral Otolaryngology Robotic Surgery (TORS) procedures restricted to benign and malignant tumors, classified at T1 and T2, and for benign base of tongue resection procedures. There are no changes in the design, technology, materials, manufacturing, performance, specifications or method of use for the *da Vinci* Surgical Systems and *EndoWrist* Instruments and Accessories associated with this premarket

notification. The *da Vinci* Surgical Systems (Models IS1200, IS2000, IS3000) consist of two integrated sub-systems as follows:

Surgeon Console and a Patient Side Cart. While seated at the Surgeon Console, the surgeon controls critical aspects of the procedure, including movement of the endoscopic instruments and endoscope within the operative field. The endoscopic instruments and camera movements are controlled by the surgeon through use of the Master Tool Manipulators (MTM); two hand-operated mechanisms residing with the Surgeon Console. The endoscopic Instruments are held in a fixed position with respect to the patient by either two (or optionally three) unique arms known as Patient Side Manipulators (PSM), which are located on the Patient Side Cart (PSC). The endoscope is also held in a fixed position (with respect to the patient) by another arm, similar to the PSM, known as the Endoscope Camera Manipulator (ECM), which is also located on the PSC. Commands from the surgeon console are relayed to the PSC, which is located immediately adjacent to the patient, via cables. Instrument and endoscopic changes are performed by another individual positioned adjacent to the PSC.

Intuitive Surgical Stereo View Endoscopic System. The Endoscopic vision system used with the *da Vinci* Surgical Systems, also known as the Intuitive Surgical Insite Vision system, consists of a stereo endoscope, endoscopic camera and various accessories, including a light source and light guides. The Insite Vision system provides two independent images that are relayed to the surgeon located at the Surgeon Console, where they are fused to form a 3-D (or alternatively a 2-D) image of the surgical field.

Intended Use:

Transoral otolaryngology surgical procedures restricted to benign and malignant tumors, classified as T1 and T2, and for benign base of tongue resection procedures.

The safety and effectiveness of this device for use in the treatment of obstructive sleep apnea have not been established.

Comparison to Predicate Device:

There are no changes in the design, technology, materials, manufacturing, performance, specifications or method of use for the Intuitive Surgical Endoscopic Instrument Control Systems or instruments.

Technological Characteristics:

The technological characteristics of the subject device are identical to the predicate device.

Summary of Clinical Data:

This premarket submission contained more than 32 published literature articles and unpublished retrospective data on 293 subjects from 3 institutions.

The majority of the 32 published articles were case series/case reports with variable objectives covering a broad range of medical conditions, different operative approaches, different combinations of procedures and devices, and variable duration of patient follow-up. Evidence to support the benign base of tongue resection procedures for the da Vinci Surgical System included published data from the following 9 articles:

Author/Year of Publication	Procedure/Indication (BOT – Base of Tongue)	No. of Patients
Cognetti 2012 ¹	BOT resection, para-pharyngeal, excision of cyst, epiglottic lesion, tumor	22/63 TORS in 33 patients had BOT
Duvvuri 2011 ²	BOT, soft palate and pharyngeal wall malignant lesions	2/10 patients had BOT
Friedman 2012 ³	Midline glossectomy (BOT)	40 patients
Hurtuk 2011 ⁴	Lingual tonsillectomy at BOT	6 patients
Lee 2012 ⁵	Lingual Tonsillectomy at BOT	21 patients
Robinson 2012 ⁶	BOT	80 patients
Andsberg 2000 ⁷	Midline glossectomy (BOT)	22 patients
Vicini 2011 ⁸	BOT for tongue base hypertrophy	N/a
Weinstein 2012 ⁹	Benign tumor, tonsillar hypertrophy, stenosis, base of tongue, neurofibroma	15

1. Cognetti DM, Luginbuhl AJ, Nguyen AL, Curry JM. Early Adoption of Transoral Robotic Surgical Program: Preliminary Outcomes. Otolaryngology Head and Neck Surgery DOI: 10.1177/0194599812443353 2012.
2. Duvvuri U, Bonawitz S, Kim S; Robotic assisted oropharyngeal reconstruction. J Robotic Surg; DOI 10.1007/s11701-0326-z, (1-6) 2011
3. Friedman Michael Friedman, MD, Craig Hamilton, MBChB, Christian G. Samuelson, MD, Kanwar Kelley, MD, JD, David Taylor, Kristine Pearson-

Chauhan, Alexander Maley, Renwick Taylor, and T. K. Venkatesan, MD. Transoral Robotic Glossectomy for the Treatment of Obstructive Sleep Apnea-Hypopnea Syndrome in Otolaryngology –Head and neck Surgery. DOI: 10.1177/0194599811434262 May 2012

4. Agnes Hurtuk, MD; Theodoros Teknos, MD; Enver Ozer, MD. Robotic-Assisted Lingual Tonsillectomy in The laryngoscope 121:July 2011
5. Jonathan M. Lee, MD; Gregory S. Weinstein, MD; Bert W. O'Malley, Jr, MD; Erica R. Thaler, MD; Transoral Robot –Assisted Lingual Tonsillectomy and UPPP for Obstructive Sleep Apnea in Annals of otology, Rhinology & laryngology; 121 (10:635-639, 2012
6. Samuel Robinson, FRACS, Suren Krishnan, OAM, FRACS, John-Charles Hodge, FRACS, Andrew Foreman, PhD, MBBS :Robot-assisted, volumetric tongue base reduction and pharyngeal surgery for obstructive sleep apnea in Operative Techniques in Otolaryngology (2012) 23, 48-55
7. Andsberg Ulf and Jessen Max: Eight Years of Follow up-Uvulopharyngoplasty combined with Midline Glossectomy as a treatment for Obstructive Sleep Apnea Syndrome: Acta Otolaryngol 2000; Suppl 543:175-178
8. Vicini C, Dallan I, Canzi P, et al. Transoral robotic surgery of the tongue base in obstructive sleep Apnea-Hypopnea syndrome: Anatomic considerations and clinical experience. Head and Neck Mar 11 2011
9. Gregory S Weinstein, Bert W. O'Malley, Jr., J. Scott Magnuson, William R Carroll, Kerry D Olsen, Lixia Daio, Eric J, F. Christopher. Transoral Robotic Surgery (TORS): A Multicenter Study To Assess Feasibility, Safety, And Efficacy. 2012 The Laryngoscope (in press).

The unpublished retrospective data on 293 subjects involved multiple surgical procedures besides lingual tonsillectomy, base of tongue resection, and partial glossectomy conducted concomitantly either using the da Vinci system or a non-robotic approach. These data supported a general indication for base of tongue resection procedures only and not an indication for the treatment of obstructive sleep apnea.

The SE with limitations now includes the following warning:

The safety and effectiveness of this device for use in the treatment of obstructive sleep apnea have not been established.

FDA clears a device with a limitation when there is a reasonable likelihood that:

1. the device will be used for an intended use not identified in the proposed labeling for the device, and
2. such use could cause harm.

Base of tongue resection is an integral step in obstructive sleep apnea procedures. The likelihood that the da Vinci Surgical Systems may be used off-label to perform obstructive sleep apnea procedures is evident from the number of published case reports and review articles, including the several articles above, citing such use.

The safety and effectiveness of the da Vinci Surgical System for treating obstructive sleep apnea cannot be determined from current published literature. There is the potential to cause death or serious injuries. Retrospective review of the above referenced literature regarding da Vinci device use for the treatment of obstructive sleep apnea procedures revealed that episodes of bleeding as being the most common serious adverse event, followed by dehydration and dysphagia. Pneumonia and hypoxemia were also noted.

The clearance for benign base of tongue resection was based on the unpublished retrospective data and the 9 published literature articles cited above.