K093217

510(k) Summary

[As Required by 21 CFR 807.92(c)]

Date:	12/22/09 JAN 21 2010
Submitter:	Intuitive Surgical, Inc. 950 Kifer Road Sunnyvale, CA 94086
Official Contact:	Meghna Sridharan *Regulatory Engineer* Ph: (408) 523-2487 Fax: (408) 523-1390 Meghna.sridharan@intusurg.com
Trade Name:	*da Vinci* Harmonic ACE™ Device ▪ 5mm Harmonic ACE™ Instrument ▪ 8mm Harmonic ACE™ Instrument ▪ Disposable Harmonic ACE™ Insert
Common Name:	Endoscopic Instrument, ultrasonic endoscopic instrument
Classification:	Endoscope and Accessories, 21 CFR 876.1500, NAY(LFL)
Predicate Device:	Intuitive Surgical, Inc. K042855, Harmonic™ Curved Shears Instrument Ethicon Endo-Surgery, Inc. K042777, Harmonic ACE™ with Hand Control
Device Description:	The Intuitive Surgical Harmonic ACE™ Device is used to deliver ultrasonic energy to enable transection and coagulation of tissue. The proximal end of the device is a re-usable instrument housing and attaches to the *da Vinci* Surgical System. The distal end is a disposable insert which consists of a shaft and grip assembly. The instrument housing and disposable insert are assembled together, attached to the *da Vinci* Surgical System and connected to Ethicon's Endo-Surgery Generator 300 (Model GEN04) using the Hand Piece (Model HP054). When the Harmonic ACE™ Device is activated, it delivers ultrasonic

energy and enables transection and coagulation of tissue. The instrument is available in 5mm and 8mm diameters and in two configurations: one for use with the *da Vinci* (IS1200); and the other for the *da Vinci S/Si* (IS2000/IS3000) Surgical Systems, respectively. The same disposable insert is used with all configurations of the instrument.

Intended Use: The Intuitive Surgical *da Vinci* Harmonic ACE™ Device is intended for soft tissue incisions when bleeding control and minimal thermal injury are desired. It is designed to be used in conjunction with the *da Vinci* Surgical Systems (Model IS1200, IS2000 and IS3000) and the Ethicon Endo-Surgery Generator 300 (Model GEN04) and Hand Piece (Model HP054).

Technological Characteristics: The subject device is equivalent in intended use, design and technology as compared to the predicate devices.

Performance Data: Performance tests (bench and animal lab tests) were conducted to demonstrate that the device is substantially equivalent to the predicate devices and that the design output meets the design input requirements. The results of the testing did not raise any new issues of safety or efficacy as compared to Intuitive Surgical's currently cleared Harmonic™ Curved Shears (K042855).

Summary: Based on the technical characteristics, intended use and performance test data, the Intuitive Surgical Harmonic ACE™ Device has been determined to be equivalent in safety, efficacy, and performance to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JAN 21 2010

Intuitive Surgical, Inc.
% Ms. Meghna Sridharan
Regulatory Engineer
950 Kifer Road
Sunnyvale, California 94086

Re: K093217
Trade/Device Name: da Vinci Harmonic ACE™ Device
Regulation Number: 21 CFR 876-1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NAY
Dated: December 22, 2009
Received: December 23, 2009

Dear Ms. Sridharan:

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. 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.

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 (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/cdrh/mdr/ 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 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/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number if known: K093217

Device Name: *da Vinci* Harmonic ACE™ Device

INDICATION FOR USE:

The Intuitive Surgical *da Vinci* Harmonic ACE™ Device is intended for soft tissue incisions when bleeding control and minimal thermal injury are desired. It is designed to be used in conjunction with the *da Vinci* Surgical Systems (Model IS1200, IS2000 and IS3000) and the Ethicon Endo-Surgery Generator 300 (Model GEN04) and Hand Piece (Model HP054).

Prescription Use __X__ (Per 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use _____ (Per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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