K112584

510(K) SUMMARY
(per 21 CFR 807.92)

SEP 29 2011

Submitter:

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

Brandon Hansen
Sr. Regulatory Affairs Manager

Date Summary Prepared: **September 2, 2011**

Device Name:

Trade Name:	***da Vinci* Harmonic ACE™ Curved Shears** • 5mm Harmonic ACE™ Curved Shears • 8mm Harmonic ACE™ Curved Shears • Disposable Harmonic ACE™ Insert **Intuitive Surgical Harmonic™ Curved Shears Instrument** • 5mm Harmonic™ Curved Shears Instrument • 8mm Harmonic™ Curved Shears Instrument • Disposable Harmonic™ Curved Shears Insert
Common Name:	Endoscopic Instrument
Classification Name:	Endoscope and Accessories (21 CFR 876.1500, Product Code NAY)

Predicate Device:

Intuitive Surgical, Inc.
K093217, Harmonic ACE™ Curved Shears

Intuitive Surgical, Inc.
K042855, Harmonic™ Curved Shears Instrument

Device Description:

The Intuitive Surgical Harmonic ACE™ Curved Shears 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 the Disposable Harmonic ACE™ Insert, which consists of a shaft and grip assembly. The instrument housing and the disposable insert are assembled together, attached to the *da Vinci* Surgical System and connected to Ethicon's Endo-Surgery Generator using the Hand Piece. When the Harmonic

ACE™ Curved Shears is activated, it delivers ultrasonic energy and enables transection and coagulation of tissue. The instrument is available in 5mm and 8mm diameters and in 2 configurations: one for the da Vinci (IS1200) and one for the da Vinci S/Si (IS2000/ IS3000) Surgical Systems, respectively. The same disposable insert is used with all configurations of the instrument.

The Intuitive Surgical Harmonic™ Curved Shears Instrument 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 Systems. The distal end is the Disposable Harmonic™ Curved Shears Insert, which consists of a shaft and grip assembly. The instrument housing and the disposable insert are assembled together, attached to the *da Vinci* Surgical Systems and connected to Ethicon's Endo-Surgery Generator using the Hand Piece. When the Harmonic ACE™ Curved Shears is activated, it delivers ultrasonic energy and enables transection and coagulation of tissue. The instrument is available in 5mm and 8mm diameters and in 2 configurations: one for the da Vinci (IS1200) and one for the da Vinci S/Si (IS2000/ IS3000) Surgical Systems, respectively. The same disposable insert is used with all configurations of the instrument.

Indications For Use:

The *da Vinci* Harmonic ACE™ Curved Shears 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 (Models IS1200, IS2000, and IS3000) and a compatible Ethicon Endo-Surgery Generator and Hand Piece.

The Intuitive Surgical Harmonic™ Curved Shears Instrument 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 (Models IS1200, IS2000, and IS3000) and a compatible Ethicon Endo-Surgery Generator and Hand Piece.

Technological Characteristics:

The subject device Harmonic ACE™ Curved Shears is identical in technological characteristics as compared

to the predicate device.

The subject device Harmonic™ Curved Shears Instrument is identical in technological characteristics as compared to the predicate device.

Performance Data: Performance testing was not required for this labeling change.

Summary: The Harmonic ACE™ Curved Shears is substantially equivalent in indications for use and technological characteristics as compared to the predicate device.

The Harmonic™ Curved Shears Instrument is substantially equivalent in indications for use and technological characteristics as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Intuitive Surgical, Inc.
% Ms. Kim T. Servance
1266 Kifer Road
Sunnyvale, California 94086

SEP 29 2011

Re: K112584
Trade/Device Name: da Vinci Harmonic ACE™ Curved Shears
Intuitive Surgical Harmonic™ Curved Shears Instrument
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NAY
Dated: September 02, 2011
Received: September 06, 2011

Dear Ms. Servance:

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. 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); 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/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 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.

Sincerely yours,

For DEP CLN DIV

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

Enclosure

6. INDICATION FOR USE

510(k) Number if known: K112584

Device Name: *da Vinci* Harmonic ACE ™ Curved Shears
Intuitive Surgical Harmonic™ Curved Shears Instrument

INDICATIONS FOR USE:

da Vinci Harmonic ACE™ Curved Shears

The *da Vinci* Harmonic ACE™ Curved Shears 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 (Models IS1200, IS2000, and IS3000) and a compatible Ethicon Endo-Surgery Generator and Hand Piece.

Intuitive Surgical Harmonic™ Curved Shears Instrument

The Intuitive Surgical Harmonic™ Curved Shears Instrument 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 (Models IS1200, IS2000, and IS3000) and a compatible Ethicon Endo-Surgery Generator and Hand Piece.

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)

Neil R. P. Ogden for mkm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112584