FEB - 4 2011

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

Date: 09/10/2010

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

Official Contact:
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Trade Name:
Intuitive Surgical Flared Cannula
- Model # 420262: 5mm Flared Cannula
- Model # 420319: 8mm Flared Cannula

Common Name: Endoscopic Instrument and Accessories

Classification:
Endoscope and Accessories,
21 CFR 876.1500, NAY(LFL)

Predicate Device:
Intuitive Surgical, Inc.
K990144, da Vinci Endoscopic Instrument Control System (Model IS1000) and Endoscopic Instruments

Device Description:
The Intuitive Surgical Flared Cannula consists of a tapered hollow tubular shaft with a flared distal tip and a bowl with an integral receptacle. The hollow shaft serves as the port of entry, the bowl is used to attach the cannula to the da Vinci Surgical System and the receptacle allows for attachment of commercially available dispersive electrode grounding pad via a 2-Pin grounding connector.

Intended Use:
The Flared Cannulae are intended to be used with the *da Vinci* Surgical System (*da Vinci S* (Model IS2000) or *da Vinci SI* (Model IS3000)) to serve as a port of entry during *da Vinci*

procedures that do not require maintenance of insufflation.

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

Performance Data: Performance tests (bench and animal lab tests) were conducted to demonstrate that the device is substantially equivalent to the predicate device 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.

Summary: Based on the technical characteristics, intended use and performance test data, the Intuitive Surgical 5mm and 8mm Flared Cannula have been determined to be equivalent in safety, efficacy, and performance 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. Meghna Sridharan
Senior Regulatory Engineer
1266 Kifer Road
Sunnyvale, California 94086

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Re: K101743
Trade/Device Name: Intuitive Surgical® Flared Cannula
Regulation Number: 21 CFR 876-1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NAY
Dated: January 27, 2011
Received: January 28, 2011

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,

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: K101743

Device Name: Intuitive Surgical Flared Cannula

INDICATION FOR USE:

The Flared Cannulae are intended to be used with the *da Vinci* Surgical System (*da Vinci S* (Model IS2000) or *da Vinci Si* (Model IS3000)) to serve as a port of entry during *da Vinci* procedures that do not require maintenance of insufflation.

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)

Mark R P Ogden for MKM

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

510(k) Number K101743