DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

February 19, 2014

Intuitive Surgical, Inc.
Mr. Brandon Hansen
Project Manager, Regulatory Affairs
1266 Kifer Road
Sunnyvale, California 94086

Re: K133845
Trade/Device Name: 8mm trocar
Regulation Number: 21 CFR 876.1500
Regulation Name: Disposable Surgical Trocar/Cannula
Regulatory Class: Class II
Product Code: GCJ
Dated: January 24, 2014
Received: January 27, 2014

Dear Mr. Hansen:

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 [OIR/IVD OPTION] and Part 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 (21 CFR Part 801 [OIR/IVD OPTION] and Part 809), 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" (21 CFR 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,

Felipe Aguel

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
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)*
K133845

Device Name
8 mm Trocar

Indications for Use *(Describe)*

The 8 mm Trocar has application in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments.

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)*

Long H. Chen -A

for BSA

(Division Sign-off)

Division of Surgical Devices 510(k) Number: K133845

510(k) Summary FEB 19 2014

510(k) Owner:	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086
Contact:	Brandon Hansen Project Manager, Regulatory Affairs Phone Number: 408-523-7485 Fax Number: 408-523-8907 Email: Brandon.Hansen@intusurg.com
Date Summary Prepared:	January 24, 2014
Trade Name:	8 mm Trocar
Common Name:	Disposable Surgical Trocar/Cannula
Classification:	Class II 21 CFR 876.1500, Laparoscope, General & Plastic Surgery
Product Code:	GCJ
Classification Advisory Committee:	General and Plastic Surgery
Predicate Device:	Unimax Trocar System (K112358)

Device Description:

The 8 mm Trocar consists of a cannula, an obturator, and a universal cannula seal. It provides a port of entry for endoscopic instruments typically through the abdominal or chest wall of the patient during endoscopic surgery. It is available in standard and long versions. The universal seal contains a valve and stopcock to allow for insufflation and the cannula has a fin for attachment to the *da Vinci* Surgical System and markings for placing the remote center in the body wall. The three components are packaged as a kit, and the obturator and cannula seal also packaged individually.

Intended Use:

To provide a port of entry for endoscopic instruments.

Indications for Use:

The 8 mm Trocar has application in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments.

Technological Characteristics:

The 8 mm Trocar is substantially equivalent to the Unimax Medical Systems, Inc., Trocar System (K112358) in terms of design, materials, technological characteristics and intended use.

Performance Data:

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

Human Factors and Usability Testing:

A summative usability validation study was conducted with users (surgeons and operating room staff) for the 8 mm Trocar. This study was conducted in a simulated operating room and involved typical workflow scenarios as well as certain troubleshooting scenarios related to safety-critical tasks. Results of the validation study and the other elements of the human factors engineering program provide evidence that the 8 mm Trocar is safe and effective when used by the intended users in the intended use environment.

Summary:

Based on the intended use, indications for use, technological characteristics, and performance data, the 8 mm Trocar is substantially equivalent to the Unimax Medical Systems, Inc., Trocar System (K112358)