DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 3, 2014

Intuitive Surgical Incorporated
Manish Patel
Regulatory Engineer
1266 Kifer Road
Sunnyvale, California 94086

Re: K143217
Trade/Device Name: 12 mm and Stapler Bladeless Obturators
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NAY, GCJ
Dated: November 7, 2014
Received: November 10, 2014

Dear Patel:

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 contact 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. 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
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 below.

510(k) Number *(if known)*
K143217

Device Name
12 mm & Stapler Bladeless Obturators

Indications for Use *(Describe)*
The Intuitive Surgical EndoWrist Stapler 45, Stapler 45 Reloads and other Stapler Accessories (including the bladeless obturators) are intended to be used with the da Vinci Surgical System (Model IS4000) for resection, transection and/or creation of anastomoses in General, Thoracic, Gynecologic, and Urologic surgery. The device can be used with staple line or tissue buttressing material (natural or synthetic).

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

510(k) Owner:	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086
Contact:	Manish Patel Regulatory Engineer Phone Number: 408-523-2185 Fax Number: 408-523-8907 Email: manish.patel@intusurg.com
Date Summary Prepared:	November 07, 2014
Trade Name:	12 mm & Stapler Bladeless Obturators
Common Name:	Endoscope and accessories
Classification:	Class II 21 CFR 876.1500, Endoscope and Accessories
Product Codes:	**NAY,** GCJ
Classification Advisory Committee:	General and Plastic Surgery
Predicate Device:	K140553 - *EndoWrist*® Stapler 45, Stapler 45 Reloads and Accessories

Device Description

The subject 12 mm & Stapler Bladeless Obturator (Bladeless Obturator) is used with the 12 mm & Stapler Cannula (Cannula) and 12 mm & Stapler Cannula Seal (Cannula Seal) to facilitate placement of the Cannula in the body wall. The Bladeless Obturator consists of three components – a shaft, a handle, and two latches that allow it to latch onto the Cannula Seal. The handle is made of Radel R-550 while the shaft and the two latches are made of stainless steel. The subject device is a reusable device and is offered in two lengths (standard and long) to match the Cannula lengths and meet users' needs.

Intended Use/Indications for Use:

The Intuitive Surgical EndoWrist Stapler 45, Stapler 45 Reloads and other Stapler Accessories (including the bladeless obturators) are intended to be used with the da Vinci Surgical System (Model IS4000) for resection, transection and/or creation of anastomoses in General, Thoracic, Gynecologic, and Urologic surgery. The device can be used with staple line or tissue buttressing material (natural or synthetic).

Technological Characteristics:

The subject 12 mm & Stapler Bladeless Obturator is very similar to its predicate device (12 mm & Stapler Blunt Obturators cleared in K140553). It has the same intended use, same fundamental scientific technology, and similar technological characteristics as the predicate device. Modifications consist of a change in tip design from blunt to bladeless and change in material of the shaft from Radel to 17-4 stainless steel.

Performance Data:

In accordance with the Design Control process, risk analysis was conducted to evaluate impact of modifications on the predicate device. Design verification and design validation testing were conducted on the subject device to confirm that the design outputs meet design input requirements and that the device is safe and effective for its intended use.

Design Verification:
The bench testing summarized in this submission verifies dimensional, mechanical and labeling requirements for the subject device. Drop test, axial load bearing capacity of the connection between the Obturator and Cannula Seal, maximum diametrical clearance when the Obturator is used with the Cannula, and maximum length of the Obturator shaft past the distal end of the Cannula were tested along with adequacy of labeling required to communicate compatibility of the subject device.

Design Validation:
The testing summarized in this submission validates general, functional, and interaction (compatibility) requirements for the subject device. Tests with an animal model were performed to assess the subject device's latching mechanism and verify that the obturator does not catch on tissue. The subject device's compatibility with Cannula and Cannula Seals were tested to ensure they maintain insufflation when used together.

Summary:

Based on the intended use, indications for use, technological characteristics, and performance data, the subject 12 mm & Stapler Bladeless Obturator is substantially equivalent to the predicate 12 mm & Stapler Blunt Obturators cleared in K140553.