



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

May 22, 2015

Key Surgical Incorporated  
Ms. Amy Yanta  
Regulatory Affairs  
8101 Wallace Road  
Eden Prairie, Minnesota 55344

Re: K151222

Trade/Device Name: Key Surgical® Cautery Tip Cleaner  
Regulation Number: 21 CFR 878.4400  
Regulation Name: Electrosurgical cutting and coagulation device and accessories  
Regulatory Class: Class II  
Product Code: GEI  
Dated: May 6, 2015  
Received: May 13, 2015

Dear Ms. Yanta:

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,

**Jennifer R. Stevenson -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

# SECTION 4

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

Form Approved: OMB No. 0910-0120  
Expiration Date: January 31, 2017  
See PRA Statement below.

## Indications for Use

510(k) Number (if known)  
K151222

Device Name  
Key Surgical® Cautery Tip Cleaner

### Indications for Use (Describe)

The disposable cautery tip cleaner is a single use sterile device intended to be used as an electrosurgical accessory to remove eschar buildup from the tips of electrosurgical cauterization blades during surgical procedures.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
PRASStaff@fda.hhs.gov

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

9/33


**SECTION 5: 510(k) Summary**
**Key Surgical® Cautery Tip Cleaners**

The summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements as required by 21 CFR 807.92.

**Date:** May 06, 2015

 Administrative Information
 

---

**Submitter:** Key Surgical, Inc.

**Establishment Registration Number:**

2183785

**Contact Person:**

Amy Yanta  
8101 Wallace Road  
Eden Prairie, MN 55344  
Regulatory Affairs  
952.288.2269

 Device Identification
 

---

**Device Name:** Cautery Tip Cleaners

**Common Name:** Cautery Tip Cleaners

**Device Classification Name:** Electrosurgical cutting and coagulation device and accessories

**Device Classification:** Class II

**Panel:** General & Plastic Surgery

**Classification Regulation:** 878.4400

**Product Code:** GEI

**Performance Standards:** No Recognized Consensus Standards

**Predicate Device:** Cautery Tip Cleaner, cleared on 01/19/2006 via K053433

**Trade Name:** None

---

10/32



## SECTION 5: 510(k) Summary

### Device Description

The disposable cautery tip cleaner is a 50mm by 50mm small foam pad with an abrasive surface, and adhesive back layer, which are used to aid in the removal of eschar on electrosurgical blades during surgical procedures. The abrasive surface is made from aluminum oxide 'gravel', with a polyurethane foam pad and polyurethane adhesive layer containing a barium monofilament for x-ray detection. The adhesive back allows for universal placement and keeps the device in place while the tip of the electrosurgical cauterization device is scratched on the abrasive surface to remove eschar buildup. The product does not come in contact with the patient, is provided sterile and is single-use.

### Statement of Intended Use

The disposable cautery tip cleaner is a single use sterile device intended to be used as an electrosurgical accessory to remove eschar buildup from the tips of electrosurgical cauterization blades during surgical procedures.

### Substantial Equivalence Discussion

The Key Surgical Cautery Tip Cleaner predicate device is the Xodus Medical, Inc., K053433, cleared on January 19, 2006. The following illustrates the similarities in the product design.

Table 2: Substantial Equivalence

Property or Characteristic	Proposed Device: Key Surgical® Cautery Tip Cleaner	Predicate Device: Cautery Tip Cleaner
Intended Use/Indications for Use	A device intended to be used to aid in the removal of eschar buildup on electrosurgical blades during surgical procedures. The cautery tip cleaner is sterile and a single use device.	The disposable Cautery Tip Cleaner is a single use sterile product. Its intended use is as an electrosurgical accessory to clean uncoated cautery blades that are part of an electrosurgical pencil. The cautery blade is "scratched" on the cautery tip cleaner to remove eschar build-up during surgical procedures to allow the cautery blade to function effectively throughout the procedure. The product is usually placed somewhere on the sterile field, typically on the mayo stand. This product does not come in contact with the patient.
Conditions of Use	Single Use, disposable	Single Use, disposable
Materials	Aluminum oxide 'gravel', with a polyurethane foam pad and polyurethane adhesive layer containing a barium monofilament for x-ray detection	Square polyurethane foam pad featuring a textile abrasive layer with an adhesive backing containing an x-ray detectable radiopaque strip.
Adhesive back	Yes, for universal placement and aid in keeping the device in place	Yes, for universal placement and aid in keeping the device in place



### SECTION 5: 510(k) Summary

Sterility	Provided Sterile	Provided Sterile
Principle of Operation	The cautery tip cleaner is used to aid in the removal of eschar on electro-surgical blades during surgical procedures	Electrosurgical accessory to clean uncoated blades that are part of an electro-surgical pencil
Interface with Electro-surgical Cauterization Blade	The Cautery Tip Cleaner does not impact the function of the electro-surgical cauterization blades. It is not required for use with the blades, but an accessory that aids in the removal of eschar buildup.	Used for the cleaning of electro-surgical cautery tips during surgical procedures.

### Performance Data Summary

Table 3: Performance Data Summary of Cautery Tip Cleaners

Requirement	Specification	Method	Result
Sterility	SAL $10^{-6}$	ISO 11137-2	Pass
Functional Requirements	Product adhesive backing must be easily removed	Removed adhesive backing from tip cleaner	Pass
Packaging	Vacuum leak test	ISO 11607, ASTM F 1980	Pass
	Dye penetration test	ASTM F 1929, ASTM F 1980	Pass
	Agar contact-attack test	ISO 11607, ASTM F 1980	Pass
	Tensile seal strength test	ASTM F 88, ASTM F 1980	Pass
	Accelerated aging test	ASTM F 1980, ISO 11737	Pass

### Substantial Equivalence Conclusion

The differences between the Cautery Tip Cleaners and the predicate device do not constitute a new intended use, and do not raise different questions of safety and effectiveness. They are both designed to aid in the cleaning of electro-surgical blades during surgical procedures.

The Cautery Tip Cleaners are substantially equivalent to the predicate device cleared under K053433.