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

October 28, 2014

Qingdao Kingston Medical Devices Ltd.
Wu Hanhua
Quality Manager
No. 5 Seoul Road
Free Trade Zone
Qingdao 266555
China

Re: K132771
Trade/Device Name: Endoscopic Surgical Instruments
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 17, 2014
Received: September 29, 2014

Dear Hanhua:

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

Indications for Use

510(k) Number (if known): K132771

Device Name: Endoscopic Surgical Instruments

Indications for Use:

Endoscopic Surgical Instruments are intended for cutting, grasping, dissecting and coagulation of soft tissue in endoscopic surgical procedures. They are intended for single patient use.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Qingdao Kingston Medical Devices Ltd.

510（k）Summary

510(k) Owner

Qingdao Kingston Medical Devices Ltd.
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Contact Person

Wu Hanhua
Quality Manager
Email:Kingston-med1@hotmail.com

Date Prepared

September 17, 2014

Name of Device

Trade Name:Kingston Endoscopic Surgical Instruments
Common Name: Endoscopic Surgical Instruments
Classification Name:Electrosurgical,cutting&coagulation&accessories
Product Code:GEI
Regulation Number:21 CFR 878.4400
Class:II

Device description

The Endoscopic Surgical Instruments are disposable,single use,individually packaged devices that are composed of biocompatible materials. The instruments are 5mm in diameter as well as 330mm (or 420mm) in length.

The instruments consist of handle, shaft and dissector /grasper/scissor jaw.

Intended use

The Endoscopic Surgical Instruments are intended for cutting, grasping,dissecting and coagulation of soft tissue in endoscopic surgical procedures.They are intended for single patient use.

Predicate Device

GENICON, Electrosurgical Instrumentation previously cleared under 510(k) K061417

Technological Characteristics

The technological characteristics are the same as or equivalent to the predicate device.

Performance Data

Evidence of safety and effectiveness was obtained from electrical safety testing and function bench testing as following:

Testing in accordance with IEC 60601-1

Testing in accordance with IEC 60601-1-2

Testing in accordance with IEC 60601-2-2

Function bench testing such as Transverse holding force,Longitudinal holding force,Ratchet holding force and Cutting efficacy,Thermal effects on Tissue.

Conclusion

Because the Endoscopic Surgical Instruments is composed of the same material,has the same design and dimensions,and is supplied sterile,it is as safe,as effective,and performs as well as the predicate device,we can conclude that the new device is substantially equivalent to the predicate device under the Federal Food,Drug,and Cosmetic Act.