May 31, 2018

Modern Medical Equipment Manufacturing Limited
Jerry Cheung
Regulatory Manager
35-41 Tai Lin Pai Rd, Unit F
5th Fl, Gold King Ind., Bldg., Kwai Chung, N.T.
Hong Kong, China

Re: K170703
Trade/Device Name: Single Use Arthroscopic Electrode (with Pencil)
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX, GEI
Dated: April 11, 2018
Received: April 20, 2018

Dear Jerry Cheung:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K170703

Device Name
Single Use Arthroscopic Electrode (with Pencil)

Indications for Use *(Describe)*
The Single Use Arthroscopic Electrodes are indicated for single-use under sterile conditions with an electrosurgical pencil, a generator, neutral electrode and contact quality monitor (CQM) to deliver monopolar radiofrequency (RF) energy to cut and excise tissue or coagulate blood vessels during arthroscopic 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.

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1. 510(k) Owner

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Telephone:	(852) 2420 9068
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Contact person:	Mr. Jerry Cheung
Date of preparation:	27 April, 2018

2. Device

Name of Device:	Single Use Arthroscopic Electrode (with Pencil)
Trade or proprietary name:	Single Use Arthroscopic Electrode; Push Button Pencil with Single Use Arthroscopic Electrode Rocker Switch Pencil with Single Use Arthroscopic Electrode
Common or usual name:	Single Use Arthroscopic Electrode; Push Button Pencil with Single Use Arthroscopic Electrode Rocker Switch Pencil with Single Use Arthroscopic Electrode
Classification name:	Arthroscope; Electrosurgical, Cutting & Coagulation Device & Accessories
Classification Panel:	General & Plastic Surgery
Product Code:	HRX, GEI
Class:	II

3. Predicate device

Aaron Arthroscopy Electrodes with 510(k) number K020579.

4. Device description

Single Use Arthroscopic Electrodes are monopolar active devices, which consists of a conductive electrode tip, an insulated shaft and a conductive post. The conductive electrode tip configuration offers 90° Angled Hook, 45° Angled Hook and Blade to meet the needs of Arthroscopy. The conductive electrode tip is the conductive portion of the electrode which delivers RF energy to cut and excise tissue or coagulate blood vessels during arthroscopic surgical procedures.

The insulated shaft is the mid portion of the electrode. It is insulated with non-conductive material

(Polyolefin Shrinkage tube and / or PTFE Shrinkage tube) in order to prevent accidental conduction of the electrosurgical current from this point to the patient. An over-mold cap is attached at the end of electrode.

The conductive post is used to plug the electrode into the distal end of an electrosurgical pencil from which it receives the electrical current. The post size of electrode is 2.36mm in diameter which fits insertion to the distal end of electrosurgical pencils in the legal market. The maximum rated accessory voltage is 2.9kVp. The maximum power setting of electrosurgical generator is 120 Watts.

The Single Use Arthroscopic Electrodes are provided in the following designs:

A. **Product Description (Electrode only):**

1. Single Use Arthroscopic Hook Electrode, 90˚ Angle, insulated, Total Length 213.5mm, Hex Lock
2. Single Use Arthroscopic Hook Electrode, 45˚ Angle, insulated, Total Length 214.5mm, Hex Lock
3. Single Use Arthroscopic Angled Blade Electrode, insulated, , Total Length 214.5mm, Hex Lock
4. Single Use Arthroscopic Angled Blade Electrode, non-insulated, Total Length 214.5mm, Hex Lock

5. Single Use Arthroscopic Hook Electrode, 90˚ Angle, insulated, Total Length 213.5mm
6. Single Use Arthroscopic Hook Electrode, 45˚ Angle, insulated, Total Length 214.5mm
7. Single Use Arthroscopic Angled Blade Electrode, insulated, Total Length 214.5mm
8. Single Use Arthroscopic Angled Blade Electrode, non-insulated, Total Length 214.5mm

9. Single Use Arthroscopic Hook Teflon coated, Electrode, 90˚ Angle, insulated, Total Length 213.5mm, Hex Lock
10. 10. Single Use Arthroscopic Hook Teflon coated, Electrode, 45˚ Angle, insulated, Total Length 214.5mm Hex Lock
11. 11. Single Use Arthroscopic Angled Blade Teflon coated Electrode, insulated, Total Length 214.5mm Hex lock
12. Single Use Arthroscopic Angled Blade Teflon coated Electrode, non-insulated, Total Length 214.5mm, Hex Lock

13. Single Use Arthroscopic Hook Teflon coated Electrode, 90˚ Angle, insulated, Total Length 213.5mm
14. Single Use Arthroscopic Hook Teflon coated Electrode, 45˚ Angle, insulated, Total Length 214.5mm
15. Single Use Arthroscopic Angled Blade Teflon coated Electrode, insulated, Total Length 214.5mm
16. Single Use Arthroscopic Angled Blade Teflon coated Electrode, non-insulated, Total Length 214.5mm

B. Product Description (Push Button Pencil with electrode):

17. Single Use Push Button Pencil with Arthroscopic Hook Electrode, 90˚

Angle, insulated, Total Length 213.5mm
18. Single Use Push Button Pencil with Arthroscopic Hook Electrode, 45˚ Angle, insulated, Total Length 214.5mm
19. Single Use Push Button Pencil with Arthroscopic Angled Blade Electrode, insulated, Total Length 214.5mm
20. Single Use Push Button Pencil with Arthroscopic Angled Blade Electrode, non-insulated, Total Length 214.5mm
21. Single Use Push Button Pencil with Arthroscopic Hook Teflon Coated Electrode, 90˚ Angle, insulated, Total Length 213.5mm
22. Single Use Push Button Pencil with Arthroscopic Hook Teflon Coated Electrode, 45˚ Angle, insulated, Total Length 214.5mm
23. Single Use Push Button Pencil with Arthroscopic Angled Blade Teflon Coated Electrode, insulated, Total Length 214.5mm
24. Single Use Push Button Pencil with Arthroscopic Angled Blade Teflon Coated Electrode, non-insulated, Total Length 214.5mm

C. Product Description (Rocker Button Pencil with electrode):

25. Single Use Rocker Switch Pencil with Arthroscopic Hook Electrode, 90˚ Angle, insulated, Total Length 213.5mm
26. Single Use Rocker Switch Pencil with Arthroscopic Hook Electrode, 45˚ Angle, insulated, Total Length 214.5mm
27. Single Use Rocker Switch Pencil with Arthroscopic Angled Blade Electrode, insulated, Total Length 214.5mm
28. Single Use Rocker Switch Pencil with Arthroscopic Angled Blade Electrode, non-insulated, Total Length 214.5mm
29. Single Use Rocker Switch Pencil with Arthroscopic Hook Teflon Coated Electrode, 90˚ Angle, insulated, Total Length 213.5mm
30. Single Use Rocker Switch Pencil with Arthroscopic Hook Teflon Coated Electrode, 45˚ Angle, insulated, Total Length 214.5mm
31. Single Use Rocker Switch Pencil with Arthroscopic Angled Blade Teflon Coated Electrode, insulated, Total Length 214.5mm
32. Single Use Rocker Switch Pencil with Arthroscopic Angled Blade Teflon Coated Electrode, non-insulated, Total Length 214.5mm

Single Use Arthroscopic Electrodes do not have cloud communications, network connection, wireless communication in any form, USB / serial ports / removable media or software upgrades.

Single Use Arthroscopic Electrode is for “Adults only” use.

DO NOT USE a Single Use Arthroscopic Electrode with port, trocar or cannula. Capacitive coupling may be associated with unintended thermal injury.

5. Intended use

The Single Use Arthroscopic Electrode is intended for use to deliver monopolar radiofrequency energy.

6. Indication for use
The Single Use Arthroscopic Electrodes are indicated for single-use under sterile conditions with an electrosurgical pencil, a generator, neutral electrode and contact quality monitor (CQM) to deliver monopolar radiofrequency (RF) energy to cut and excise tissue or coagulate blood vessels during arthroscopic surgical procedures.

7 Technological characteristic
Single Use Arthroscopic Electrodes have substantially equivalent construction and performance as the predicate devices.

8. Substantial Equivalence
The technological characteristics and performance testing of the subject and predicate devices are substantially equivalent. .

9. Performance Testing Data
Validation and Verification testing was performed on device sterility in accordance with ISO 11135:2014 and packaging.

Performance Testing included comparative device use on porcine tissue: kidney, liver, muscle and bovine tendon in saline for both Cut mode and Coagulation mode in accordance with the Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery Guidance for Industry and Food and Drug Administration Staff, Document issued on August 15, 2016.

The duty cycle is 10 seconds ON and 5 seconds OFF. This testing demonstrated that the thermal effect and tissue stickiness on the tip of electrode of the subject and predicate devices are substantially equivalent.

9. Safety and Biocompatibility testing data
Electrical Safety complies with
IEC60601-1:2005 + CORR. 1 (2006) + CORR. 2 (2007)
IEC60601-2-2: 2009 (Fifth Ed)

The proposed device is an external device that contacts tissue/bone/dentin for limited contact duration (less than 24 hours). No biologically significant effect was observed in tests conducted in accordance with ISO 10993 for intracutaneous reactivity, in vitro cytotoxicity, skin sensitization, acute systemic toxicity or pyrogenicity.

10. Conclusion
Based on comparing technological characteristic and performance testing data, the subject device, Single Use Arthroscopic Electrodes is substantially equivalent to predicate device (K020579).