July 19, 2018

Cathay Manfacturing Corp.
% Ren Ren
Manager
No. 328, Xishe Road
Maogang Town, Songjiang Area
Shanghai, China 201607

Re: K170369
Trade/Device Name: Disposable Electrosurgical Pencils, CP1001 Series
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 3, 2018
Received: July 3, 2018

Dear Ren Ren:

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 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)*
K170369

Device Name
Disposable Electrosurgical Pencils (CP1001 Series)

Indications for Use *(Describe)*
The Disposable Electrosurgical Pencil is used for cutting and coagulation to remove tissue and control bleeding by using high frequency during electrosurgical with a specified Electrosurgery Unit (ESU) generator. The device is disposable for single use and supplied as sterile with an electrode tip.

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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CATHAY MANUFACTURING CORP.

510(k) Summary

Submitter: CATHAY MANUFACTURING CORP.
No. 328, Xishe Road, Maogang Town, Songjiang Area
Shanghai, CN 201607

Contact: Ms. Ren, Ren
Phone: (86)021-57878328
Email: rubyfantasy@qq.com

Date Prepared: July. 6, 2018

Device Trade Name: **Disposable Electrosurgical Pencils**
Model: **CP1001 Series**

Device Common Name: **Disposable Electrosurgical Pencils**
Classification Name: **Electrosurgical cutting and coagulation device and accessories**
Class: **II**

Classification Name: 21 CFR 878.4400

Product Code: **GEI**

Predicate Device:

Device	Company	Product Code	510(k) Number
OBS Disposable Electrosurgical Pencils	Jiangmen City Xinhui Baisheng Medical Equipment Co., Ltd	GEI	K092634

1. **Indication for Use:**
   The Disposable Electrosurgical Pencil is used for cutting and coagulation to remove tissue and control bleeding by using high frequency during electrosurgical surgery with a specified Electrosurgery Unit (ESU) generator. The device is disposable for single use and supplied as sterile with an electrode tip.

2. Product Description:

The Disposable Electrosurgical pencils are used for the cutting and coagulation of soft tissue and have a conductive cable which is designed for use with high frequency surgical generator (Electrosurgical unit).

The connector or plug fits into electrosurgical unit. The hand-pieces are made of plastic with two buttons (cutting and coagulation buttons) in the case of the hand-controlled pencils, while the foot controlled pencils is activated by a monopolar footswitch connected to the generator. One button or switch is to control the cutting mode, CUT, of the ESU while the other controls the coagulation mode, COAG.

The applied electrosurgery, monopolar, is the emittance of the high frequency alternating current, HFAC, from the diathermy via an active electrode through the patient's body tissues and then returned back to the diathermy machine via a dispersive electrode (patient return pad).

The proposed device mainly consists of electrode tip, hand piece handle, cable, and plug. For all applied device models, only one kind of dimension of electrode tip, standard hex blade electrode is available. However, two kind of cable length, 3m or 5m, and three kind of available hand-piece color, white/blue/green color, are available

4. Summary of Technology Characteristics and Performance Testing (Comparison to the Predicate Device)

ELEMENT OF COMPARISON	SUBJECT DEVICE	Predicate Device K092634 OBS Disposable Electrosurgical Pencils
Indications for Use	used for cutting and coagulation to remove tissue and control bleeding by using high frequency during electrosurgical surgery with a specified Electrosurgery Unit (ESU) generator. The device is disposable for single use and supplied as sterile with an electrode tip.	used for cutting and coagulation to remove tissue and control bleeding by using high frequency during electrosurgical surgery with a specified Electrosurgery Unit (ESU) generator. The device is disposable for single use and supplied as sterile with an electrode tip.
Classification	878.4400	878.4400
Product Code	GEI	GEI
OTC or Prescription	For Prescription Use	For Prescription use
Energy source type	RF Energy	RF Energy
Sterility and for single use	Yes, Sterile and for single use	Yes, Sterile and for single use
Sterilization method	EO Sterilization	EO Sterilization
Monopolar or Bipolar electrode	Monopolar electrode	Monopolar electrode
Electrode materials	Stainless steel	Stainless steel
Electrode insulation material	ABS	ABS
Electrode coating	N/A	N/A
Electrode shape and dimensions	standard hex blade electrode, 2.36 x 70mm	standard hex blade electrode, 2.36 x 70mm; other shape and dimensions
Shaft materials	ABS	ABS
Handle length	95 mm	90 mm

Shaft length	50mm	50 mm
Total length	145mm	140mm
Shaft diameter	2.36 mm	2.36 mm
Cable materials	Blue PVC cable	Blue PVC cable
Cable length	3m or 5m	3m or 5m
Foot control model	Yes, has foot control mode	Yes, has foot control mode
Standards applied	IEC 60601-1; IEC 60601-2-2; ISO 11135; ISO 11607	IEC 60601-1; IEC 60601-2-2; ISO 11135; ISO 11607
Biocompatibility	Conforms to ISO10993	Conforms to ISO10993
Labeling	confirm to 21 CFR Part 801	confirm to 21 CFR Part 801
Performance	Conforms to IEC 60601-1 and IEC 60601-2-10:2012, Part 2 particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories. Performance conforms the requirements specified in 'Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery'	Conforms to IEC 60601-1 and IEC 60601-2-10:2012, Part 2 particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories Performance conforms the requirements specified in 'Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery'
Stability and shelf life	3 year	3 year

5. Bench Testing (non-clinical):

Compare to predicate product specified in K092634, our device and the predicate device are same in Essential Components, raw materials, physical features, and same manufacturing processes. The biocompatibility performance equivalence evidence of proposed electrode can be demonstrated.

And also following the 'Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery, the proposed Disposable Electrosurgical Pencils had evaluated the Performance of Thermal effects on tissues, comparing with reference device specified in K092634. Three tissue types, liver, kidney and muscle tissue, were used for this evaluation by measuring the thermal damage zone sizes (length, width, and depth).

The comparison tests conclusively prove that the proposed electrode is similar / equivalence in the performance of thermal effects on tissues as the predicate device device.

The safety performances of subject device are demonstrated by the Third party, TUV Rheiland, through testing following IEC 60601-1:2005+CORR. 1(2006) + CORR.2(2007), Part 1General requirements for basic safety and essential performance, and IEC 60601-2-2:2009, Medical electrical equipment -Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories.

The results of bench testing & type testing provide reasonable assurance that the proposed device has been designed and validated to assure conformance to the requirements for its indication for use.

Package integrity and functional performance testing were completed on the subject device following aging and real time stability tests to support the proposed shelf life.

6. Conclusion:

Based on the indication for use, technology characteristics, and performance testing, the proposed product, Disposable Electrosurgical Pencils, has been shown to be appropriate for its indication for use and is considered to be substantially equivalent to the predicate device.