# 510(k) Summary

**Sponsor:**

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## 1. Device information:

| | |
|---|---|
| Proprietary Name: | Disposable Neutral Electrode |
| Model: | GP202 |
| Regulation Description | Electrosurgical cutting and coagulation device and accessories |
| Product Code | GEI |
| Submission Type | 510(k) |
| Regulation Number | 21 CFR 878.4400 |
| Device Class | 2 |

## 2. Predicate Devices

K102372
Trade/Device Name: OBS Disposable Electrosurgical Pads
Models: GBS-Db, GBS-Dm
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories,
Regulatory Class: Class II
Product Code: GEI

**Manufactured by:**
Jiangmen City Xinhui BaiSheng Medical Equipment Co., Ltd.

## 3. Description of the device

The Disposable Neutral Electrode, is an accessory for high voltage high frequency electrosurgical devices, connect it to the body of the PATIENT and the HF SURGICAL

EQUIPMENT, it can perform it function for provide a return path for the HIGH FREQUENCY current and unwanted burns are avoided.

Construction --- The product consists of Electrode, Electrode carrier and Clarity PET. It is packed in an al film bag.

The electrode is composed of conductive gel, aluminum foil, sponge, anti-sticking film and connecting wire. Conductive gel is composed of high molecular monomer, glycerinum and water, which is a gel, can be conducted in high frequency and has voltage-sensitive by polymerization.

**4. Indications for Use**

This disposable neutral electrode for adult patients with conductive adhesive gel is used as neutral reference during electrosurgical procedures.

**5. Testing**

Laboratory testing was conducted to validate and verify that the Disposable Electrosurgical Pencil met all design specifications, including electrical safety, EMC, biocompatibility, specification. Results of these tests demonstrate compliance to the requirements of all consensus standards

**6. Compared to the predicate device**

Disposable Neutral Electrode has been carefully compared to legally marketed devices with respect to intended use, appearance, essential components, materials and performance specifications.

They are similar in intended use, appearance, essential components, materials and performance specifications. Although they may differ from the predicate devices in color and size, it won't affect safety and effectiveness of subject devices.

In addition, performance and safety testing have been done to validate the performance and safety of the device.

**7.0 Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence is as below:**

Electrical safety test, Mechanical performance test, and Biocompatibility test have been done to demonstrate the safety and performance of subject devices. Tests was conducted in accordance with the "510(k) Guidance Document for General Surgical Electrosurgical Devices", which outlines safety and performance requirements.

The proposed device is equivalent to the identified predicate device with respect to technological characteristics and function. The device has been designed to comply with the applicable sections of ANSI/AAMI American National Standard for Electrosurgical Devices:
The International Standard for electrical medical device: IEC60601-1; the International

Standard for Electrosurgical Devices: IEC 60601-2-2; Biocompatibility: ISO 10993-5 and ISO 10993-10.

None of the test demonstrated and design characteristics that violated the requirements of the above mentioned standards or resulted in any safety hazards.

**8.0 Conclusions:**

The comparison and validation results presented in this 510k notification, show that the GP202 Disposable Neutral Electrode is substantially equivalent to predicated devices and are safe and effective in their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

August 22, 2013

Cathay Manufacturing Corporation
% Taizon EBO Information Technology Co., Ltd.
Zhang Hui
No. 328, Xishe Road, Maogang Town, Songhang Area
Shanghai, China 201607

Re: K130027
Trade/Device Name: Disposable Neutral Electrode GP202
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 15, 2013
Received: July 25, 2013

Dear Zhang Hui:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K130027
Device Name: Disposable Neutral Electrode

Indications for Use:

This disposable neutral electrode for adult patients with conductive adhesive gel is used as neutral reference during electrosurgical procedures.

| Prescription Use __X__ (Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use ____ (21 CFR 801 Subpart C) |
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Joshua C. Nipper -S

(Division Sign-off)
Division of Surgical Devices
510(k) Number K130027