



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

November 5, 2015

Guangzhou Jinxinbao Electronic Co.,ltd  
% Helen Nan  
General Manager  
Wenzhou Cytech Information Service Co., Ltd.  
Room302, No.21 Building, Kaiyu Garden, Xishan South Road  
Wenzhou, Zhejiang, 325000  
China

Re: K150923  
Trade/Device Name: BR128 Breast Pump  
Regulation Number: 21 CFR 884.5160  
Regulation Name: Powered Breast Pump  
Regulatory Class: II  
Product Code: HGX  
Dated: December 20, 2014  
Received: September 8, 2015

Dear Helen Nan,

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" (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.

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,

  
**Herbert P. Lerner -S**

for Benjamin R. Fisher, Ph.D.  
Director  
Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

### Indications for Use

510(k) Number (if known)  
K150923

Device Name  
BR128 Breast Pump

Indications for Use (Describe)

The BR128 Breast Pump is an electrically powered suction device intended to express and collect milk from a lactating woman's breasts. This is for a single user.

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.

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## 510(k) Summary

(As required by 21 CFR 807.92(a))

### 1.0 Submitter Information

- Company: Guangzhou Jinxinbao Electronic Co.,Ltd
- Address: No.38 Huanzhen Xi Road, Dagang Town, Panyu, Guangzhou,  
Guangdong, 511470, CHINA
- Phone: 086-20-34938449
- Fax: 086-20-22865301
- Contact: Jiacheng Guo, General Manager
- Date: November 5, 2015

### 2.0 Device Information

- Trade/Device Name: BR128 Breast Pump

· Trademark: The trademark 'Rycom' is written in a green, italicized, sans-serif font. The letter 'R' is larger and more prominent, with a blue underline that extends under the 'y' and 'c'. A registered trademark symbol (®) is located to the upper right of the 'm'.

- Common Name: Powered Breast Pump

- Classification: Device: Pump, Breast, Powered

Regulation Description: Powered breast pump

Review Panel: Obstetrics/Gynecology

Product Code: HGX

Submission Type: 510(K)

Regulation Number: 21 CFR 884.5160

Device Class: II

### 3.0 Predicate Device Information

Evenflo Advanced Double Electric Breast Pump

submitted by Evenflo Feeding, Inc.

510K Number: K131153



**4.0 Device Description**

The BR128 is an electrically powered breast pump that uses negative pressure to express milk from the breasts of lactating women. It adopts a Single-Chip Microcomputer to imitate a baby’s suckling action and a reciprocating vacuum pump to generate the suction to extract the milk at vacuum levels between 0 and 170mmHg. It is intended for single pumping.

It is designed to mechanically interface with a mother’s breast via a massage cushion and withdraw then collect the breast milk. The motor unit of the device is connected to the bottle via a silicone tube. Its suction strength is adjustable via the suction adjustment button on the device, but its cycles per minute are controlled by software and cannot be adjusted. The device can be powered by batteries or the provided mains adapter.

**5.0 Indications for Use**

The BR128 Breast Pump is an electrically powered suction device intended to express and collect milk from a lactating woman’s breasts. This is for a single user.

**6.0 Comparison with the Predicate Device**

Comparison Table of Technological Characteristic with the Predicate Device

<b>Device &amp; Predicate Device(s):</b>	<b>Subject Device: BR128 Breast Pump  (K150923)</b>	<b>Predicate Device: Evenflo Advanced Double Electric Breast Pump  (K131153)</b>
<b>Intended Use</b>		



*Guangzhou Jinxinbao Electronic Co.,Ltd*

Intended Use	An electrically powered suction device intended to express and collect milk from a lactating woman's breasts. This is for a single user.	An electrically powered suction device intended to express and collect milk from a lactating woman's breasts. This is for a single user.
Patient Population	Lactating women	Lactating women
Environment of Use	Home	Home
Prescription Designation	OTC	OTC
Single User	Yes	Yes
<b>General Device Characteristics</b>		
Pump Style	Reciprocating Vacuum Pump	Reciprocating Vacuum Pump
Single/Double	Single	Double/Single
Adjustable Suction Levels	Yes	Yes
Adjustable Cycle Rates	No	Yes
Stimulating Velocity	100-150 cycles/min	30-80 cycles/min
Stimulating Intensity	0-170mmHg	50-270mmHg (single)
Sucking Velocity (Cycle Rate)	13-18 cycles/min	30-80 cycles/min
Sucking Intensity	0-170mmHg	50-270mmHg (single)
Overflow Protection	No	Yes
Pressure Modulation Control	Microprocessor	Microprocessor
Software	Yes	Yes
Power Source	AC adaptor or 2 AA Batteries	AC adaptor or 6 AA batteries



Cleaning Method for Accessories	Boiling water	Boiling water
Patient Contact Material	Silicone, PP, ABS (have been verified by relevant ISO 10993 standards)	Unknown
Food Contact Material	PP & Silicone (have been evaluated by relevant food criteria as set forth in 21 Code of Federal Regulations)	Unknown

The subject device has the same intended use as the predicate device.

The subject and predicate device have the following technological characteristics in common:

- Both use reciprocating vacuum pump
- Both have adjustable suction levels
- Both are controlled by software
- Both have the same power source

However, the subject and predicate device have the following differences in technological characteristics.

- Pumping Options (single vs. sing/double)
- Suction Pressure
- Cycle Speed
- Overflow Protection
- Patient Contacting Material

These differences do not raise different questions of safety or effectiveness.

**7.0 Discussion of Tests Performed**



## **7.1 Clinical Tests**

Clinical testing was not performed for BR128 Breast Pump as part of the submission.

## **7.2 Non-Clinical Tests**

The subject device was tested/analyzed according to the following standards in order to ensure its safety:

**Biocompatibility** according to AAMI / ANSI / ISO 10993-5:2009/(R) 2014, Biological Evaluation of Medical Devices -- Part 5: Tests for In Vitro Cytotoxicity (L929 Assay) and AAMI / ANSI / ISO 10993-10:2010, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization. (Vaginal Irritation and Guinea Pig Maximization Sensitization)

**Electrical Safety** according to AAMI / ANSI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005, Mod). (General II (ES/EMC))

**Electromagnetic Compatibility** according to AAMI / ANSI / IEC 60601-1-2:2007/(R)2012, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests (Edition 3). (General II (ES/EMC))

**Safety of Food Contact Materials** according to FDA 21 CFR 177.2600 and FDA 21 CFR 177.1520



**Software Validation** per the FDA Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," dated May 11, 2005.

**Use Life** based on evaluation of device specifications following simulated use testing.

**Performance Testing** including minimum and maximum pressure testing, cycle speed, sound volume, and low voltage alert testing.

### **8.0 Conclusion:**

The subject device - BR128 Breast Pump is substantially equivalent to the predicate device – Evenflo Advanced Double Electric Breast Pump (K131153).