



Food and Drug Administration  
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Ningbo Youhe Electrical Appliance Technology Co., Ltd.  
% Daniel Qiu  
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Room 1301, Bld 46, Jing Gu Zhong Rd., No.58,  
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Re: K163136  
Trade/Device Name: Youha electric breast pump, Models: YH-8004, YH-8016,  
YH-8006IV, YH-8015  
Regulation Number: 21 CFR§ 884.5160  
Regulation Name: Powered Breast Pump  
Regulatory Class: II  
Product Code: HGX  
Dated: June 22, 2017  
Received: June 22, 2017

Dear Daniel Qiu:

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,

Joyce M. Whang -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)

K163136

Device Name

Youha electric breast pump, Models: YH-8004, YH-8016, YH-8006IV, YH-8015

Indications for Use (Describe)

The Youha electric breast pump is intended to be used by lactating women to express and collect milk from their breasts. It is intended 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.

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## 510(k) Summary

**K163136**

### 1. Submitter Information

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Contact Person: Huang Yun Jun

2. **Date Prepared:** June 30, 2017

### 3. Device Information

Trade Name: Youha electric breast pump  
Common Name: Powered breast pump  
Models: YH-8004, YH-8016, YH-8006IV, YH-8015  
Regulation Class: Class II  
Regulation Number: 21CFR 884.5160, Powered breast pump  
Review Panel: Obstetrics/Gynecology  
Product Code: HGX (pump, breast, powered)

### 4. Predicate Device

510(k): K162415  
Device Name: Spectra 9 Plus powered breast pump  
Manufacturer: Uzinmedicare Company

### 5. Device Description

The Youha electric breast pump is a single-user, powered breast pump intended to be used by lactating women to express and collect milk from their breasts. YH-8004 and YH-8016 have both single (pumping from one breast) and double pumping (pumping from both breasts) configurations. YH-8006IV and YH-8015 have a single pumping configuration only.

A reciprocating diaphragm vacuum pump, driven by a microprocessor, generates the suction to extract the milk at vacuum levels up to 280mmHg. The user interface consists of a front panel keypad and LCD display in which the user switches between modes and controls the vacuum pressure.

The device has three modes of operation:

- **Massage mode:** Suction patterns with fast cycles and low vacuum to start milk flowing

- Low expression mode: Suction patterns with slow cycles and high vacuum to express more milk gently and efficiently.
- High expression mode: Suction patterns with slower cycles and higher vacuum to express more milk efficiently.

YH-8004, YH-8015 and YH-8016 have 3 modes including massage mode, low expression mode and high expression mode. YH-8006IV has 2 modes including massage mode and high expression mode.

The device is electrically powered from either an internal rechargeable battery or an external AC power adapter. The external adapter also charges the battery.

## 6. Indications for Use

The Youha electric breast pump is intended to be used by lactating women to express and collect milk from their breasts. It is intended for a single user.

## 7. Predicate Comparison

The following table compares the Youha Electric breast pump to the predicate device with respect to indications for use and technological characteristics:

Device & Predicate Device(s):	Subject Device: Youha electric breast pump <a href="#">K163136</a>		Predicate Device: Spectra 9plus <a href="#">K162415</a>
<b>Indications for Use</b>	The Youha electric breast pump is intended to be used by lactating women to express and collect milk from their breasts. It is intended for a single user.		The Spectra 9Plus is a single-user, powered breast pump intended to express and collect milk from the breasts of lactating women.
<b>Single user</b>	Yes		Yes
<b>Provided Non-sterile</b>	Yes		Yes
<b>Re-usable</b>	Yes		Yes
<b>Direct user contact</b>	Yes		Yes
<b>Power source</b>	AC/DC wall converter and Rechargeable		Power source
<b>Suction Strength (Expression Mode) (mmHg)</b>	Low	YH-8004:75-250	50-270
		YH-8016:75-250	
		YH-8015:115-250	
		YH-8006IV:N/A	
	High	YH-8004:120-280	
		YH-8016:120-280	
		YH-8015: 120-280	
		YH-8006IV:125-280	
<b>Suction Strength (Massage Mode) (mmHg)</b>	YH-8004:34-190		50-150
	YH-8016:34-190		
	YH-8015: 50-190		
	YH-8006IV: 50-190		
<b>Adjustable Suction levels</b>	Yes		Yes
<b>Suction Settings (High/low)</b>	YH-8004:6		10

<b>Expression Mode)</b>	YH-8016:6		
	YH-8015:9		
	YH-8006IV:10		
<b>Suction Settings (Massage Mode)</b>	YH-8004:6		5
	YH-8016:6		
	YH-8015:9		
	YH-8006IV:10		
<b>Cycle Speed (Expression Mode) (cycles/min)</b>	Low	YH-8004:41-69	24-60
		YH-8016:41-69	
		YH-8015:36-60	
		YH-8006IV:N/A	
	High	YH-8004: 16-33	
		YH-8016:16-33	
		YH-8015: 16-34	
		YH-8006IV:32-57	
<b>Cycle Speed (Massage Mode)</b>	YH-8004:94-113		70
	YH-8016:94-113		
	YH-8015:80-122		
	YH-8006IV:71-100		
<b>Backflow Protection</b>	Yes		Yes
<b>Single or Double Pumping</b>	YH-8004/ YH-8016: Single and Double Pumping YH-8006IV/YH-8015:Single Pumping Only		Single and Double Pumping
<b>Visual Indicator</b>	LCD		LCD
<b>Pump Type</b>	Diaphragm		Diaphragm

The Youha electric breast pump has the same intended use but different technological characteristics compared to the predicate device. The differences in technological characteristics do not raise different questions of safety and effectiveness.

## 8. Non-Clinical Performance Testing

Non-clinical tests were conducted to verify that the Youha electric breast pump met all design specifications and is substantially equivalent to the predicate. The test results demonstrated that the proposed device complies with the following standards:

- Risk Analysis developed in accordance with ISO 14971:2007.
- Electrical Safety Testing in accordance with IEC 60601-1:2005 (3rd Edition) with US deviations per AAMI/ANSI ES 60601-1:2005/(R)2012 and A1:2012.
- Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2:2014.
- Safety Testing for use in the home in accordance with IEC 60601-1-11:2015.
- Biocompatibility Tests in accordance with ISO-10993, including cytotoxicity (ISO 10993-5:2009), sensitization (ISO 10993-10:2010) and irritation (ISO 10993-10:2010).
- Software Validation – Software Life Cycle Processes in accordance with IEC 62304.

- FDA’s Guidance Document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.” (May 11, 2005).

Performance testing was conducted at minimum and maximum vacuum settings to determine the minimum and maximum vacuum levels of the pump as compared to its specifications. The specifications were met for vacuum level, cycle rate, and backflow protection. These results held under conditions of single and double pumping mode with varying power sources (e.g., AC/DC power vs. battery power).

## **9. Clinical Performance Data**

Not Applicable

## **10. Conclusion**

Based on the comparison and analysis above, the Youha electric breast pump is substantially equivalent to the predicate device.