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## Registration Confirmation

Facility: HANGZHOU REALY TECH CO LTD, Hangzhou, Zhejiang, CHINA

You have successfully entered your facility registration and device listing information. You should print a copy of this page for your records. Listing numbers appear below for the products manufactured, developed, or processed at this facility.

**As a manufacturer, specification developer, or single-use device reprocessor, you are required to pay an annual fee for medical device facility registration.**

**You will receive another e-mail providing you with your registration number in approximately 30 to 90 days. Until your registration number is assigned, reference your Owner/Operator number in any correspondence with the Center for Devices and Radiological Health.**

**Your registration will be valid through Dec 31, 2020. An e-mail will be sent to the Owner/Operator and the Official Correspondent 90 days before the facility is required to re-register for Fiscal Year 2020 with instructions on how and when to re-register.**

**Note: Registering your device facility and listing your devices does not, in any way, constitute FDA approval of your facility or your devices.**

Should you have any questions, please send an e-mail to [reglist@cdrh.fda.gov](mailto:reglist@cdrh.fda.gov) (<mailto:reglist@cdrh.fda.gov>).

The Owner/Operator Number for this Registration is: 10067314

### Facility Information

**Registration Number:**

**Initial Importer:**

N

**Facility Name:**

HANGZHOU REALY TECH CO LTD

**Address:**

4th Floor, #12 Building, Eastern Medicine Town,, Xiasha Economic & Technology Development  
Hangzhou, Zhejiang, 310018, CHINA

**DUNS Number:**

010973590

**Foreign Trade Zone:**

N

**Facility URL:**

**Other Business Trade Name(s):**

## Owner/Operator Information

**Owner/Operator Number:**  
10067314

**Contact Name:**  
Pengfei Ding

**Company:**  
HANGZHOU REALY TECH CO LTD

**Address:** 4th Floor, #12 Building, Eastern Medicine Town, , Xiasha Economic & Technology Development  
Hangzhou, ZHEJIANG, 310018, CHINA

**Telephone:**  
86 - 571 - 56050793

**Fax:**  
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**E-mail:** Corporate@oneill.us.com

**DUNS Number:**  
010973590

## Official Correspondent Information

**Contact Name:**  
MICHAEL O'NEILL

**Company:**  
O'NEILL LLC

**Address:** 14 JOHN DAVENPORT DR , Suite 400  
Rome, GEORGIA, 30165, UNITED STATES

**Telephone:**  
302 - 3736061

**Fax:**  
-

**E-mail:** michael@oneill.us.com

**DUNS Number:**

## United States Agent Information

**Contact Name:**  
MICHAEL O'NEILL

**Contact Title:**  
Mr

**Business Name:**  
O'NEILL LLC

**Address:** 14 JOHN DAVENPORT DR , Suite 400  
Rome, Georgia, 30165, UNITED STATES

**Phone:**

**302 - 3736061**

**Fax:**

**DUNS Number:**

**E-mail:**

**michael@oneill.us.com**

### Device Listings

Listing Number	Premarket Submission Number/Type	Product Code(s)	Device Name(s)	Activities	Importers
D385804	Enforcement Discretion	QKO	Reagent, coronavirus serological	Manufacturer	O'Neill LLC

**Date of Initial Registration: Sat Apr 04 11:23:40 EDT 2020**