DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 17, 2017

Procare Industrial Co., Limited
% Jonathan Hu
Technical Manager
Gebiao Standard (Shanghai)
Yangpu District Liaoyuan East Road Shangyang
First Suite No.33 Room 303
Shanghai, 200093 CN

Re: K162917
Trade/Device Name: Allerhope® Allergy Skin Tester
Regulation Number: N/A
Regulation Name: N/A
Regulatory Class: Unclassified
Product Code: LDH
Dated: July 15, 2017
Received: July 18, 2017

Dear Jonathan Hu:

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,

Lori A. Wiggins -S6

Lori A. Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162917

Device Name
Allerhope® Allergy Skin Tester

Indications for Use *(Describe)*
The Allerhope® Allergy Skin Tester is for the percutaneous administration of diagnostic allergenic extracts.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K162917

Date Prepared: Aug 8th, 2017

510(k) Summary

[As required by 21 CFR 807.92]

1. Submitter's Information

Name of Sponsor:	Procare Industrial Co., Limited
Address:	No. 5-2-9-160, Science Avenue 89, Hi-Tech Zone, Zhengzhou, Henan, China
Contact Name:	Wang Yanhong
Telephone No.:	+86-13673363790
Fax No.:	+86-371-56663999
Email Address:	allergypricktest@aliyun.com

2. Correspondent's Information

Company Name:	Gebiao Standard (Shanghai)
Correspondent Name:	Jonathan HU
Telephone No.:	+86-15618986636
Email Address:	hfk1102@163.com

3. Trade Name, Common Name, Classification

Trade Name:	Allerhope ® Allergy Skin Tester
Common Name:	Allergy Skin Tester
Mode Name:	PROSPT, PROSPT II
Regulation Classification	N/A
Product Code:	LDH
Classification Panel:	General Hospital
Device Class:	Unclassified

4. Identification of Predicate Device(s)

The identified predicate within this submission is as follows:

The Multi-Test II of Lincoln Diagnostics, Incorporated have been cleared by FDA through 510(k) No. K961918 (Decision Date – Aug 7, 1996).

5. Description of the Device

Allerhope Allergy skin tester is a sterile, disposable, multiple test head applicator used to administer skin test substances. When used to apply allergenic extracts it provides a quick, convenient, and standardized procedure.

6. Indication for Use

The Allerhope® Allergy Skin Tester is for the percutaneous administration of diagnostic allergenic extracts.

7. Technological Characteristics

The working situation and environment of Allerhope® Allergy Skin Tester is the same as that of the Multi-Test II of Lincoln Diagnostics, the technological characteristics of this product is designed to make same as that of the equivalence product. A comparison of technological characteristics is provided in the following table:

Technological Characteristics	Subject Device	Predicate Device
Product Code	LDH	LDH
Intended Use	The Allergy Skin Tester is for the percutaneous administration of diagnostic allergenic extracts.	The sole indication for Multi-Test II is for the percutaneous administration of diagnostic allergenic extracts.
Product Structure	Multiple heads and points	Multiple heads and points
Material for Tester Body	Acrylic plastic (PMMA)	Acrylic plastic (PMMA)
Color Additive	Titanium dioxide	Titanium dioxide
Sterilization Method	Gamma sterilization	EO sterilization
Packaging Method	Sterilization Pouch	Sterilization Pouch

8. Discussion of Non-clinical Testing

The Allerhope® Allergy Skin Tester has been conducted related non-clinical tests to identify the substantial equivalence from the predicate device. The tests include the concerning of the biocompatibility, sterility and performance, which are demonstrated in the table below:

Characteristic	Standards Followed	Testing Conducted
Biocompatibility	ISO10993-5:2009	In Vitro Cytotoxity Test
	ISO10993-10:2010	Skin Sensitization Test Skin Irritation Test
	ISO10993-11:2006	Acute Systemic Toxicity Test
	USP_NF32<85>	Endotoxin Test
Sterility	ISO11737-2:2009	Sterility Test
Performance	ISO178:2010	Flexural Properties Test
	ISO180:2000	Lzod Impact Strength Test

9. Substantial Equivalence

The intended uses, the operation methods, and the product theories of the subject device and the predicate's are same.

The sterilization method is replaced by gamma radiation, and the SAL=10-6 can be assured.

Two models in submission: PROSPT and PROSPT II have applied the structure of heads with points which is same as the predicate.

A comparison test over allergenic extracts delivery function has been conducted between subject device and predicate device. The result shows that the subject device can carry extracts as predicate device.

It is the conclusion that such difference between the subject and the predicate do not affect any of the intended use as the predicate device. And it is substantially equivalent to predicate devices in design, function, materials, operational principles and intended use.

10. Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Procare Industrial Co., Limited concludes that Allerhope® Allergy Skin Tester is substantially equivalent to predicate device.