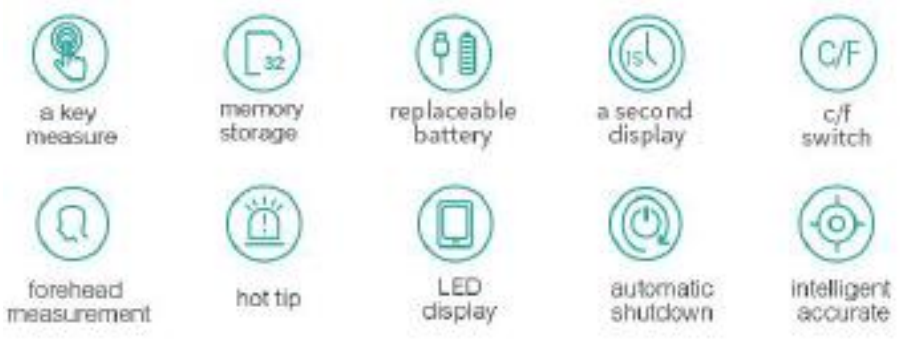
Non-Contact

IR Thermometer

AET-R1B1

Parameter

- Model： AET-R1B1
- Size: 144x101x63 mm
- Weight： 88g
- Accuracy: +/-0.2°C(35.0°C~42°C);
  +/-0.3°C(32.0°C~34.9°C/ 42.1.0°C~42.2°C);
- Automatic Shutdown： 60S
- Range: 32°C --- 42.2°C
- Display: LED Digital display
- Voltage: 2X1.5V Batteries: Size AAA
- Product life: 2 years



Features


RAPID INDUCTION
ACCURATE MEASUREMENT
·Highly sensitive infrared probe·
·Noncontact measurement·
·1 second can be measured·
Medical Infrared Thermometer
AET-R1B1

Features

LED Digital Display

The black display box focuses the reading, the screen no longer changes color, only bright font. reading clear, and easy to get the temperature value.

Features

1 second measurement

High sensitive probe, the temperaturecan be measured in 1 second, after a measurement without other operations, you can enter the next measurement it is suitable for multi-person measurement or multi-time measurement.

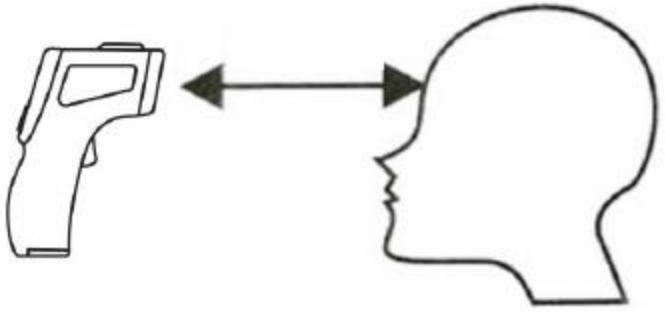
Features

Ergonomic Design Comfortable to Hold

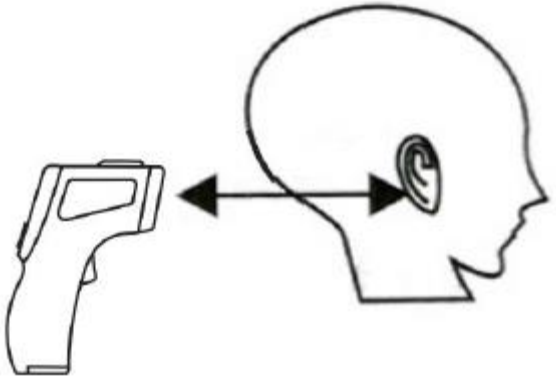
Following ergonomic design rules,
the body is solid and stable,handiness,
comfortable grip, firm grasp

Method of Measurement

Measurement 1



Measurement 2



About 3-5cm between thermometer to target

Color

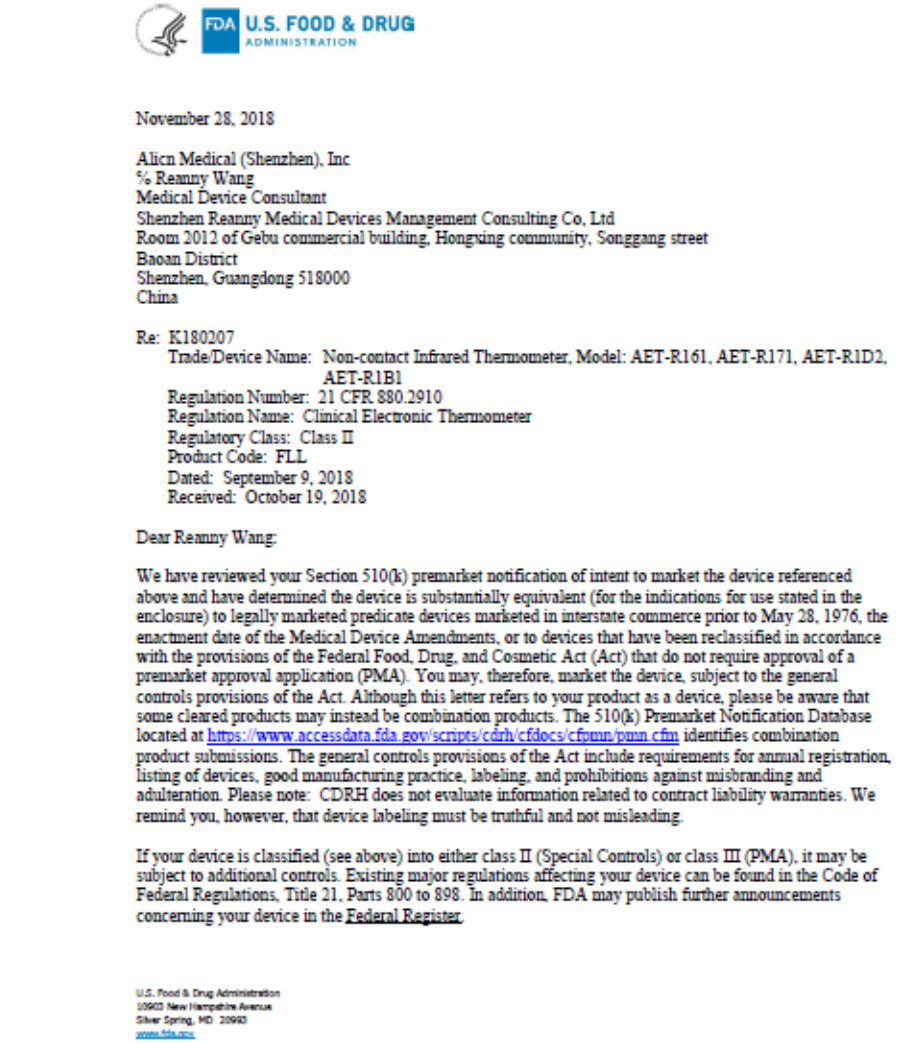
Packing

- Each products in a gift box
- Gift box: 120x175x50mm
- 42 gift boxes / carton
- Carton: 380x370x375mm
- N.W: 4.6kg
- G.W: 6.6kg

0.053 CBM per Carton

Certification

CE FDA



FDA U.S. FOOD & DRUG ADMINISTRATION

November 28, 2018

Alicn Medical (Shenzhen), Inc
% Reanny Wang
Medical Device Consultant
Shenzhen Reanny Medical Devices Management Consulting Co, Ltd
Room 2012 of Gebu commercial building, Hongxing community, Songgang street
Baoan District
Shenzhen, Guangdong 518000
China

Re: K180207
Trade/Device Name: Non-contact Infrared Thermometer, Model: AET-R161, AET-R171, AET-R1D2, AET-R1B1
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: September 9, 2018
Received: October 19, 2018

Dear Reanny Wang:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 078453 0014 Rev. 01

Manufacturer: Alicn Medical Shenzhen, Inc
4/F, B Building
Shenfubao Modern Optical Factory, Kengzi Street
Pingshan District
518122 Shenzhen City
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Alicn Medical Shenzhen, Inc
4/F, B Building, Shenfubao Modern Optical Factory, Kengzi Street, Pingshan District, 518122 Shenzhen City, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Clinical Infrared Thermometer, Electronic Thermometer and Blood Pressure Monitor

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: GZ1805201

Valid from: 2019-07-15
Valid until: 2022-05-07

Date, 2019-07-15

Stefan Preiß
Head of Certification/Notified Body

Page 1 of 1
TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH · Certification Body · Ridlerstraße 65 · 80339 Munich · Germany

TÜV®

MANY THANKS!!!