

K213082 Non-contact Infrared Thermometer, Models JXB-315, JXB-319, JXB-320, JXB-311Jan 28, 2022
127 days to decisionK213082 · Product code: FLL · General Hospital
Source: <https://www.510kdatabase.net/k213082/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Sep 23, 2021
Decision date	Jan 28, 2022
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Guangzhou Berrcom Medical Device Co., Ltd.
Location	Guangzhou, CN
Contact	Zhigang Du
510(k) history	6 submissions · 6 cleared · 2019-2023

REGULATORY CONSULTANT

Consulting firm	Shenzhen Joyantech Consulting Co., Ltd.
Contact	Yoyo Chen

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213082/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026