

K182656 JAMBRO Single Core A Sterilization wrapJun 11, 2019
259 days to decisionK182656 · Product code: **FRG** · General Hospital
Source: <https://www.510kdatabase.net/k182656/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Sep 25, 2018
Decision date	Jun 11, 2019
Days to decision	259 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jiangsu Zhande Medical Supplies Co., Ltd.
Location	Nanjing, CN
Contact	Chanjuan Xu
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Mdi Consultants, Inc.
Contact	Jigar Shah

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/k182656/> 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 June 28, 2026