

K203208 Guardian Angel Rx GA2000 Series Digital Vital Sign Monitoring SystemJun 12, 2022
590 days to decisionK203208 · Product code: **DQA** · Anesthesiology
Source: <https://www.510kdatabase.net/k203208/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Oct 30, 2020
Decision date	Jun 12, 2022
Days to decision	590 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Taiwan Aulisa Medical Devices Technologies, Inc.
Location	Taipei, TW
Contact	Paul Liu
510(k) history	9 submissions · 9 cleared · 2017-2025

REGULATORY CONSULTANT

Consulting firm	Don Mizota
Contact	Don Mizota

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/k203208/>; 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 26, 2026