

K211487 MAF GuardDec 8, 2021
209 days to decisionK211487 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k211487/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Mask, Surgical (FXX)
Date received	May 13, 2021
Decision date	Dec 8, 2021
Days to decision	209 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Maf Clothing Pvt Ltd Unit-3
Location	Karnataka, IN
Contact	Kirit Jagani
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Benjamin L. England and Associates, LLC
Contact	Thomas C. Knott

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211487/> 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