

K220378 Sparta 3-Ply Surgical Disposable Face MaskJun 30, 2022
140 days to decisionK220378 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k220378/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Feb 10, 2022
Decision date	Jun 30, 2022
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sparta East, LLC
Location	Medley, FL, US
Contact	Ricardo Samayoa
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Thomas Regulatory Resolutions, Inc.
Contact	Dallas L. Thomas

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/k220378/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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