

K211097 Banyan USA Surgical Mask Level 3Sep 22, 2021
162 days to decisionK211097 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k211097/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Mask, Surgical (FXX) |
| Date received | Apr 13, 2021 |
| Decision date | Sep 22, 2021 |
| Days to decision | 162 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Banyan USA, LLC |
| Location | Hauppauge, NY, US |
| Contact | Ricardo Ryan |
| 510(k) history | 1 submissions · 1 cleared · 2021-2021 |

REGULATORY CONSULTANT

| | |
|-----------------|------------------------------|
| Consulting firm | Mdi Consultants, Inc. |
| Contact | Timothy Kania |

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/k211097/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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