

K240916 Surgical Face Mask (Tie on/ Ear loops)Oct 18, 2024
198 days to decisionK240916 · Product code: **FXX** · General HospitalSource: <https://www.510kdatabase.net/k240916/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Mask, Surgical (FXX) |
| Date received | Apr 3, 2024 |
| Decision date | Oct 18, 2024 |
| Days to decision | 198 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Xiantao Daoqi Plastic Co., Ltd. |
| Location | Xiantao, CN |
| Contact | Honghong Bie |
| 510(k) history | 1 submissions · 1 cleared · 2024-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240916/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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