

K201691 Single-Use Surgical Mask With Ear LoopSep 17, 2020
87 days to decisionK201691 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k201691/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jun 22, 2020
Decision date	Sep 17, 2020
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Qiqihar Hengxin Medical Supplies, Ltd.
Location	Qiqihar, CN
Contact	Sihui Xiong
510(k) history	2 submissions · 2 cleared · 2020-2021

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