

K201853 Naton Disposable Surgical Face MaskApr 23, 2021
291 days to decisionK201853 · Product code: **FXX** · General HospitalSource: <https://www.510kdatabase.net/k201853/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jul 6, 2020
Decision date	Apr 23, 2021
Days to decision	291 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Naton Biotechnology (Beijing) Co., Ltd.
Location	Beijing, CN
Contact	Shanshan Zou
510(k) history	1 submissions · 1 cleared · 2021-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201853/> 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 27, 2026