

K182766 Cufitec Surgical MaskJan 3, 2019
97 days to decisionK182766 · Product code: **OUK** · General Hospital
Source: <https://www.510kdatabase.net/k182766/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgical Mask With Antimicrobial/antiviral Agent (OUK)
Date received	Sep 28, 2018
Decision date	Jan 3, 2019
Days to decision	97 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nbc Meshtec, Inc.
Location	Hino, JP
Contact	Tomokazu Nagao
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Globizz Corporation
Contact	Takahiro Haruyama

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/k182766/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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