

K231741 ProGear® Surgical Mask with Oxafence®, Model AV82030Sep 5, 2024
449 days to decisionK231741 · Product code: **OUK** · General Hospital
Source: <https://www.510kdatabase.net/k231741/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgical Mask With Antimicrobial/antiviral Agent (OUK)
Date received	Jun 14, 2023
Decision date	Sep 5, 2024
Days to decision	449 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Prestige Ameritech
Location	Fort Worth, TX, US
Contact	Hofheinz Danica
510(k) history	5 submissions · 5 cleared · 2006-2024

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