

K201421 Dukal Corporation Level 2 Surgical Mask with Ear Loops

Feb 5, 2021
252 days to decision

K201421 · Product code: FXX · General Hospital
Source: <https://www.510kdatabase.net/k201421/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	May 29, 2020
Decision date	Feb 5, 2021
Days to decision	252 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Dukal Corporation Level 2 Surgical Mask with Ear Loops and Face Shield; Dukal Corporation Level 2 Surgical Mask with Adjustable Tie Ons

APPLICANT

Company	Dukal Corporation
Location	Hauppauge, NY, US
Contact	Megan Quevedo
510(k) history	7 submissions · 7 cleared · 2007-2022

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k201421/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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