

K190308 Medicom SafeMask Sofskin Pediatric Procedure Earloop Face Masks (ASTM Level 1), Medicom SafeMask Sofskin Pediatric Procedure Earloop Face Masks, Medicom SafeMask Premier Pediatric Procedure Earloop Face Masks (ASTM Level 1), Medicom SafeMask Premier Pediatric Procedure Earloop Face Masks (ASTM Level 1)

Sep 17, 2019
217 days to decision

K190308 · Product code: **OXZ** · General Hospital
Source: <https://www.510kdatabase.net/k190308/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pediatric/child Facemask (OXZ)
Date received	Feb 12, 2019
Decision date	Sep 17, 2019
Days to decision	217 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Amd Medicom, Inc.
Location	Pointe-Claire, Montreal, CA
Contact	Ronald Reuben
510(k) history	2 submissions · 2 cleared · 2019-2020

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k190308/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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