

K191051 ARGOSMay 16, 2019
27 days to decisionK191051 · Product code: **MXK** · Ophthalmic
Source: <https://www.510kdatabase.net/k191051/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Analysis, Anterior Segment (MXK)
Date received	Apr 19, 2019
Decision date	May 16, 2019
Days to decision	27 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Santec Corporation
Location	Komaki, JP
Contact	Changho Chong
510(k) history	2 submissions · 2 cleared · 2015-2019

REGULATORY CONSULTANT

Consulting firm	Third Party Review Group, LLC
Contact	DAVE YUNGVIRT

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/k191051/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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