FDA 510(k) Premarket Notification

K191051 ARGOS

CLEARED

May 16, 2019
27 days to decision

K191051 · 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