FDA 510(k) Premarket Notification

K182659 Galilei G6 Lens Professional

CLEARED

Jul 25, 2019
303 days to decision

K182659 · Product code: **MXK** · Ophthalmic
Source: https://www.510kdatabase.net/k182659/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Analysis, Anterior Segment (MXK)
Date received	Sep 25, 2018
Decision date	Jul 25, 2019
Days to decision	303 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Sis Ag, Surgical Instrument Systems**
Location	Port, CH
Contact	Frank Ziemer
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**Regulatory Insight, Inc.**
Contact	Kevin Walls

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov