

**K182659 Galilei G6 Lens Professional**Jul 25, 2019  
303 days to decisionK182659 · Product code: **MXK** · Ophthalmic  
Source: <https://www.510kdatabase.net/k182659/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Insight, Inc.</b>
Contact	Kevin Walls

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

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