

**K170409 PASCAL Synthesis Twinstar Ophthalmic Scanning  
Laser System**Sep 12, 2017  
214 days to decisionK170409 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k170409/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 10, 2017
Decision date	Sep 12, 2017
Days to decision	214 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Topcon Medical Laser Systems, Inc. (Tmls)</b>
Location	Pleasant Hill, CA, US
Contact	Sweta Srivastava
510(k) history	2 submissions · 2 cleared · 2012-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k170409/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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