

**K213623 iTEAR100 Neurostimulator**Mar 16, 2022  
120 days to decisionK213623 · Product code: **QKV** · Ophthalmic  
Source: <https://www.510kdatabase.net/k213623/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electromechanical Tear Stimulator (QKV)
Date received	Nov 16, 2021
Decision date	Mar 16, 2022
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Olympic Ophthalmics</b>
Location	Issaquah, WA, US
Contact	Michael Gertner
510(k) history	1 submissions · 1 cleared · 2022-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hogan Lovells US LLP</b>
Contact	Janice Hogan

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213623/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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