FDA 510(k) Premarket Notification

K213623 iTEAR100 Neurostimulator

CLEARED

Mar 16, 2022
120 days to decision

K213623 · Product code: **QKV** · Ophthalmic
Source: https://www.510kdatabase.net/k213623/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Janice Hogan

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