

**K240615 Leos Laser and Endoscopy System**Apr 3, 2025  
394 days to decisionK240615 · Product code: **HQF** · Ophthalmic  
Source: <https://www.510kdatabase.net/k240615/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Ophthalmic (HQF)
Date received	Mar 5, 2024
Decision date	Apr 3, 2025
Days to decision	394 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Beaver-Visitec International, Inc.</b>
Location	Waltham, MA, US
Contact	Christopher Brady
Website	<a href="https://www.bvi.com">https://www.bvi.com</a>
510(k) history	1 submissions · 1 cleared · 2025-2025

Beaver-Visitec International, Inc. is a medical device company with a manufacturing facility in Waltham, US. The company specializes in Ophthalmic devices and systems for surgical and clinical applications. The company has received FDA 510(k) clearance from total submission. Beaver-Visitec International, Inc. maintains a focused portfolio in the Ophthalmic category, which represents 100% of its regulatory submissions. The company achieved its first clearance in 2025 and remains active in FDA regulatory pathways. Recent cleared devices include laser and endoscopy systems d...