

K153769 R:GEN Laser SystemOct 5, 2016
280 days to decisionK153769 · Product code: **HQF** · Ophthalmic
Source: <https://www.510kdatabase.net/k153769/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Ophthalmic (HQF)
Date received	Dec 30, 2015
Decision date	Oct 5, 2016
Days to decision	280 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Lutronic Corporation
Location	North Reading, MA, US
Contact	Jhung Won Vojir
510(k) history	29 submissions · 29 cleared · 2007-2025

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