FDA 510(k) Premarket Notification

K222205 Cold Sore Device (Model: QPZ-01)

CLEARED

Oct 7, 2022
74 days to decision

K222205 · Product code: **OKJ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k222205/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Treatment For Cold Sores Herpes Simplex Virus-1 (OKJ)
Date received	Jul 25, 2022
Decision date	Oct 7, 2022
Days to decision	74 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Light Tree Ventures Europe B.V.**
Location	Den Haag, NL
Contact	Alain Dijkstra
510(k) history	12 submissions · 12 cleared · 2022-2025