FDA 510(k) Premarket Notification

K220430 Capsulo

CLEARED

May 12, 2022
86 days to decision

K220430 · Product code: **HQF** · Ophthalmic
Source: https://www.510kdatabase.net/k220430/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Ophthalmic (HQF)
Date received	Feb 15, 2022
Decision date	May 12, 2022
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Quantel Medical**
Location	Cournon D'Auvergne-Cedex, FR
Contact	Bruno Pages
Website	https://www.quantelmedical.com
510(k) history	30 submissions · 30 cleared · 2000-2026

REGULATORY CONSULTANT

Consulting firm	**O'Connell Regulatory Consultants, Inc.**
Contact	Maureen O'Connell

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