FDA 510(k) Premarket Notification

K232417 MR Q

CLEARED

Jan 25, 2024
167 days to decision

K232417 · Product code: **HQF** · Ophthalmic
Source: https://www.510kdatabase.net/k232417/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Ophthalmic (HQF)
Date received	Aug 11, 2023
Decision date	Jan 25, 2024
Days to decision	167 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement
Other names	MR Q SUPINE; MR Q SLT

APPLICANT

Company	**Meridian AG**
Location	Thun, Bern, CH
Contact	Eric Odenheimer
510(k) history	6 submissions · 6 cleared · 2002-2024

REGULATORY CONSULTANT

Consulting firm	**Regulatory Insight, Inc.**
Contact	Kevin Walls

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