FDA 510(k) Premarket Notification

K231011 Merilas 532 shortpulse, Merilas 577 shortpulse, Merilas 810 shortpulse

CLEARED

Sep 12, 2023
155 days to decision

K231011 · Product code: **HQF** · Ophthalmic
Source: https://www.510kdatabase.net/k231011/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Ophthalmic (HQF)
Date received	Apr 10, 2023
Decision date	Sep 12, 2023
Days to decision	155 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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