FDA 510(k) Premarket Notification

K130933 SOLUTIS

CLEARED

Aug 2, 2013
120 days to decision

K130933 · Product code: **HQF** · Ophthalmic
Source: https://www.510kdatabase.net/k130933/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Ophthalmic (HQF)
Date received	Apr 4, 2013
Decision date	Aug 2, 2013
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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