FDA 510(k) Premarket Notification

K180895 Alleye

CLEARED

Jun 27, 2018
83 days to decision

K180895 · Product code: **HOQ** · Ophthalmic
Source: https://www.510kdatabase.net/k180895/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Grid, Amsler (HOQ)
Date received	Apr 5, 2018
Decision date	Jun 27, 2018
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Oculocare Medical AG**
Location	Zurich, CH
Contact	Lucas Bachmann
510(k) history	1 submissions · 1 cleared · 2018-2018