FDA 510(k) Premarket Notification

CLEARED

K142398 Integre Pro Scan Green, Integre Pro Scan Yellow, Integre Pro Scan Red-Green, Integre Pro Scan Red-Yellow

Jul 14, 2015
321 days to decision

K142398 · Product code: **HQF** · Ophthalmic
Source: https://www.510kdatabase.net/k142398/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Ophthalmic (HQF)
Date received	Aug 27, 2014
Decision date	Jul 14, 2015
Days to decision	321 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Ellex Medical Pty, Ltd.**
Location	Adelaide, South Australia, AU
Contact	KEVIN HOWARD
510(k) history	13 submissions · 13 cleared · 1997-2022