FDA 510(k) Premarket Notification

K102651 ISCREEN VISION SCREENER

CLEARED

Jan 12, 2011
120 days to decision

K102651 · Product code: **HKI** · Ophthalmic
Source: https://www.510kdatabase.net/k102651/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Sep 14, 2010
Decision date	Jan 12, 2011
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Iscreen Vision, Inc.**
Location	Cordova, TN, US
Contact	BUCK BROWN
510(k) history	1 submissions · 1 cleared · 2011-2011