FDA 510(k) Premarket Notification

K173474 RetiCapture

CLEARED

Jul 27, 2018
260 days to decision

K173474 · Product code: **HKI** · Ophthalmic
Source: https://www.510kdatabase.net/k173474/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Nov 9, 2017
Decision date	Jul 27, 2018
Days to decision	260 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ilooda Co,., Ltd.**
Location	Gwonseon-Gu, Suwon-Si, KR
Contact	Yun-Jung Ha
510(k) history	16 submissions · 16 cleared · 2015-2024