FDA 510(k) Premarket Notification

K053333 EAGLEVISION GELLANSERTS, MODEL REF 0040

CLEARED

May 2, 2006
152 days to decision

K053333 · Product code: **LZU** · Ophthalmic
Source: https://www.510kdatabase.net/k053333/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plug, Punctum (LZU)
Date received	Dec 1, 2005
Decision date	May 2, 2006
Days to decision	152 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Eagle Vision, Inc.**
Location	Bethesda, MD, US
Contact	JEFF COBB
510(k) history	7 submissions · 7 cleared · 1988-2006