FDA 510(k) Premarket Notification

K012852 EX-PRESS MINATURE GLAUCOMA IMPLANT, MODELS R-20, R-30, R-50, STS VERSIONS

CLEARED

Mar 26, 2002
214 days to decision

K012852 · Product code: **KYF** · Ophthalmic
Source: https://www.510kdatabase.net/k012852/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Eye Valve (KYF)
Date received	Aug 24, 2001
Decision date	Mar 26, 2002
Days to decision	214 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Optonol, Ltd.**
Location	Rockville, MD, US
Contact	RICHARD E LIPPMAN
510(k) history	2 submissions · 2 cleared · 2002-2003