FDA 510(k) Premarket Notification

K013646 ROSE K POST GRAFT LENS

CLEARED

May 30, 2002
206 days to decision

K013646 · Product code: **HQD** · Ophthalmic
Source: https://www.510kdatabase.net/k013646/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lens, Contact (other Material) - Daily (HQD)
Date received	Nov 5, 2001
Decision date	May 30, 2002
Days to decision	206 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Rose K International , Ltd.**
Location	Hamilton, NZ
Contact	IAN JENNINGS
510(k) history	2 submissions · 2 cleared · 1995-2002