

**K010126 PROSTHETIC, GELFLEX ALPHA, (POLYMACON)
HYDROPHILIC CONTACT LENS FOR DAILY WEAR (CLEAR
AND TINTED)**Mar 12, 2001
55 days to decisionK010126 · Product code: LPL · Ophthalmic
Source: <https://www.510kdatabase.net/k010126/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Jan 16, 2001
Decision date	Mar 12, 2001
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	CI-Tinters
Location	Colts Neck, NJ, US
Contact	MARTIN S KNOPF
510(k) history	3 submissions · 3 cleared · 1998-2001

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