

**K024045 CONTAFLEX GM3 49% (ACOFILCON B) SPHERICAL
SOFT CONTACT LENS FOR DAILY WEAR (CLEAR AND
TINTED, LATHE-CUT)**Feb 14, 2003
70 days to decisionK024045 · Product code: LPL · Ophthalmic
Source: <https://www.510kdatabase.net/k024045/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Dec 6, 2002
Decision date	Feb 14, 2003
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Contamac, Ltd.
Location	Littleton, CO, US
Contact	MARTIN DALSGING
Website	http://www.contamac.com/
510(k) history	18 submissions · 18 cleared · 2002-2022

Contamac, Ltd. is the world's largest manufacturer of contact and intraocular lens materials. The company develops specialist polymers and biocompatible materials for medical applications, with a manufacturing facility in Littleton, US. Contamac does not manufacture finished lenses; instead, it supplies raw materials to lens manufacturers globally. Contamac has received FDA 510(k) clearances from total submissions since 2002. The company specializes exclusively in Ophthalmic devices, with its latest clearance in 2022. All submissions have been cleared, reflecting a strong...